

# **EXHIBIT B**

Steven B. MacLean, Ph.D., P.E.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

Master File No. 2:12-MD-02327  
MDL 2327

JOSEPH R. GOODWIN, U.S. DISTRICT JUDGE

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

This document relates to the cases listed below:

Mullins, et al. v. 2:12-cv-02952  
Ethicon, Inc., et al.

Sprout, et al. v. 2:12-cv-07924  
Ethicon, Inc., et al.

Iquinto v. Ethicon, 2:12-cv-09765  
Inc., et al.

Daniel, et al. v. 2:13-cv-02565  
Ethicon, Inc., et al.

Dillon, et al. v. 2:13-cv-02919  
Ethicon, Inc., et al.

Webb, et al. v. 2:13-cv-04517  
Ethicon, Inc., et al.

Martinez v. Ethicon, 2:13-cv-04730  
Inc., et al.

McIntyre, et al. v. 2:13-cv-07283  
Ethicon, Inc., et al.

Oxley v. Ethicon, 2:13-cv-10150  
Inc., et al.

(CAPTION CONTINUED ON FOLLOWING PAGE)

VIDEOTAPED DEPOSITION OF  
STEVEN B. MACLEAN, Ph.D., P.E.  
September 29, 2015

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1	Atkins, et al. v. Ethicon, Inc., et al.	2:13-cv-11022	1
2	Garcia v. Ethicon, Inc., et al.	2:13-cv-14355	2
3	Lowe v. Ethicon, Inc., et al.	2:13-cv-14718	3
4	Dameron, et al. v. Ethicon, Inc., et al.	2:13-cv-14799	4
5	Mullens, et al. v. Ethicon, Inc., et al.	2:13-cv-16564	5
6	Shears, et al. v. Ethicon, Inc., et al.	2:13-cv-17012	6
7	Javins, et al. v. Ethicon, Inc., et al.	2:13-cv-18479	7
8	Barr, et al. v. Ethicon, Inc., et al.	2:13-cv-22606	Videotaped deposition of STEVEN B. MACLEAN, Ph.D., P.E., held at the offices of Butler Snow LLP, 1170 Peachtree Street, Suite 1900, Atlanta, Georgia, on Tuesday, September 29, 2015, at 9:42 a.m., pursuant to Agreement before Michelle M. Boudreaux, a Registered Professional Reporter in the State of Georgia.
9	Lambert v. Ethicon, Inc., et al.	2:13-cv-24393	12
10	Cook v. Ethicon, Inc., et al.	2:13-cv-29260	13
11	Stevens v. Ethicon, Inc., et al.	2:13-cv-29918	14
12	Harmon v. Ethicon, Inc., et al.	2:13-cv-31818	15
13	Snodgrass v. Ethicon, Inc., et al.	2:13-cv-31881	16
14	Miller v. Ethicon, Inc., et al.	2:13-cv-32627	17
15	(CAPTION CONTINUED ON FOLLOWING PAGE)		18
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1	Matney, et al. v. Ethicon, Inc., et al.	2:14-cv-09195	1
2	Jones, et al. v. Ethicon, Inc., et al.	2:14-cv-09517	2
3	Humbert v. Ethicon, Inc., et al.	2:14-cv-10640	3
4	Gillum, et al. v. Ethicon, Inc., et al.	2:14-cv-12756	On behalf of the Plaintiffs: 4 DANIEL THORNBURGH, Esq. 5 BRANDON MORRIS, Esq. 6 Aylstock, Witkin, Kreis & Overholtz, PLLC 7 17 E. Main Street, Suite 200 8 Pensacola, Florida 32502 9 850.202.1010 10 dthornburgh@awkolaw.com 11 bmorris@awkolaw.com
5	Whisner, et al. v. Ethicon, Inc., et al.	2:14-cv-13023	
6	Tomblin v. Ethicon, Inc., et al.	2:14-cv-14664	
7	Schepleng v. Ethicon, Inc., et al.	2:14-cv-16061	
8	Tyler, et al. v. Ethicon, Inc., et al.	2:14-cv-19110	On behalf of the Defendants: 9 CHAD R. HUTCHINSON, Esq. 10 Butler Snow LLP 11 Suite 1400 12 1020 Highland Colony Parkway 13 Ridgeland, Mississippi 39157 14 601.948.5711 15 chad.hutchinson@butlersnow.com
9	Kelly, et al. v. Ethicon, Inc., et al.	2:14-cv-22079	
10	Lundell v. Ethicon, Inc., et al.	2:14-cv-24911	Videographer: Josh Coleman
11	Cheshire, et al. v. Ethicon, Inc., et al.	2:14-cv-24999	
12	Burgoyne, et al., v. Ethicon, Inc., et al.	2:14-cv-28620	
13	Bennett, et al., v. Ethicon, Inc., et al.	2:14-cv-29624	
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<p>1           THE VIDEOGRAPHER: We are now on the  2 record. My name is Josh Coleman. I'm the  3 videographer for Golkow Technologies.  4 Today's date is September 29th, 2015. The  5 time is approximately 9:42 a.m.</p> <p>6           This video deposition is being held in  7 Atlanta, Georgia in the matter of In Re  8 Ethicon, Inc. Pelvic Repair Systems Product  9 Liability Litigation for the United States  10 District Court of the Southern District of  11 West Virginia, Charleston Division. The  12 deponent is Dr. Steve B. MacLean.</p> <p>13          If counsel will please introduce  14 themselves for the record.</p> <p>15          MR. THORNBURGH: Dan Thornburgh for the  16 plaintiffs.</p> <p>17          MR. MORRIS: Brandon Morris for the  18 plaintiffs.</p> <p>19          MR. HUTCHINSON: Chad Hutchinson,  20 counsel for Ethicon and Johnson &amp; Johnson.</p> <p>21          THE VIDEOGRAPHER: The court reporter is  22 Michelle Boudreaux and will now swear in the  23 witness.</p> <p>24          ///</p>	<p>1           same time.  2           (Discussion off the written record.)  3           (Exhibit 1 marked for identification.)</p> <p>4          Q (By Mr. Thornburgh) Did you bring any  5 documents with you responsive to the deposition notice?</p> <p>6          A I did. It was actually in electronic form,  7 but, yes, I did.</p> <p>8          Q Okay. I also see some --</p> <p>9          MR. HUTCHINSON: Counsel, you got a copy  10 for me?</p> <p>11          MR. THORNBURGH: Yeah. Sorry. I  12 figured you'd have the notice.</p> <p>13          Q (By Mr. Thornburgh) I see that there are  14 some notebooks stacked up behind you over here. What  15 are in those notebooks?</p> <p>16          A I have three notebooks I brought with me  17 today. The first notebook that's in front of me  18 consists of my two reports that were submitted in this  19 matter, as well as a few select documents from the  20 seven-year dog study at the back of the notebook.</p> <p>21          And then to my left on the ground, I have two  22 additional notebooks. One is the set of documents that  23 consists of the microcrack committee documents from the  24 1980s that was furnished by counsel. And then I have a</p>
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<p>1           STEVEN B. MACLEAN, Ph.D., P.E.,  2 being first duly sworn, was examined and testified as  3 follows:</p> <p>4           EXAMINATION</p> <p>5          BY MR. THORNBURGH:</p> <p>6          Q Good morning, Doctor.</p> <p>7          A Good morning.</p> <p>8          Q Dr. MacLean, is that -- am I pronouncing it  9 correctly?</p> <p>10         A You are.</p> <p>11         Q Doctor, I'm going to mark as Exhibit No. --  12 well, first off, you understand my name is Dan  13 Thornburgh and I represent the plaintiffs in this  14 litigation, right?</p> <p>15         A I do.</p> <p>16         Q All right. And you understand that there are  17 37 plaintiffs?</p> <p>18         A I do.</p> <p>19         Q Okay.</p> <p>20         MR. THORNBURGH: And go ahead and mark  21 as Exhibit No. 1 the notice of deposition.</p> <p>22         Q (By Mr. Thornburgh) While she's going that,  23 Doctor, did you bring any documents with you -- oh, I'm  24 sorry, she can't -- she can't write and type at the</p>	<p>1           series of select documents from production as a  2 separate notebook.</p> <p>3          Q Okay. So let's go ahead and do a couple  4 things. I'm going to mark as Exhibit No. 2 the  5 notebook that you have in front of you, which is your  6 expert report and some select documents from the dog  7 study --</p> <p>8          A That's correct.</p> <p>9          Q -- is that correct?</p> <p>10         A That is correct.</p> <p>11         (Exhibit 2 marked for identification.)</p> <p>12         Q (By Mr. Thornburgh) And then we will mark a  13 Exhibit No. 3 a second binder, which says "Deposition  14 Materials, September 29th, 2015."  15         (Exhibit 3 marked for identification.)</p> <p>16         Q (By Mr. Thornburgh) And this -- what's  17 contained -- briefly, what's contained in this Exhibit  18 No. 3?</p> <p>19         A So briefly, there are select documents from  20 the universe of produced documents in the matter, as  21 well as expert reports for a few of the plaintiffs'  22 experts.</p> <p>23         Q Okay.</p> <p>24         A And this, by the way, is all duplicative to</p>

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<p>1 what's going -- what I'm going to hand you on this 2 thumb drive.</p> <p>3 Q Okay, we'll get to the thumb drive in a 4 minute.</p> <p>5 A Sure.</p> <p>6 Q As Exhibit No. 4, we'll mark a binder that is 7 titled "1980s Microcrack Committee Documents." 8 (Exhibit 4 marked for identification.)</p> <p>9 Q (By Mr. Thornburgh) Okay. And then 10 Exhibit -- I see that you have two thumb drives over 11 there.</p> <p>12 A I do.</p> <p>13 Q Okay, so --</p> <p>14 A One is for you, plaintiffs, and one is for 15 defense. They're identical. 16 (Exhibit 5 marked for identification.)</p> <p>17 Q (By Mr. Thornburgh) Okay. And what's 18 contained within the thumb drive?</p> <p>19 A All -- my entire case file.</p> <p>20 Q And we'll get to it in more detail in a 21 little bit, but I did see that you had some -- as part 22 of your expert report, you had conducted some studies 23 or analyzed some studies of degraded polypropylene -- 24 pristine mesh or pristine Prolene that was degraded</p>	<p>1 A The envelope used to contain the two thumb 2 drives that I just presented to you.</p> <p>3 Q Okay. Is there anything written on the 4 envelope --</p> <p>5 A Nothing.</p> <p>6 Q -- front or back?</p> <p>7 A Nothing.</p> <p>8 Q Okay. All right, so let's set these out of 9 the way of the video. Put them right here for now, 10 okay?</p> <p>11 A Sure, fine.</p> <p>12 Q We'll refer to them as we go throughout the 13 day, and if you need to refer to any item within those 14 exhibits, just feel free to pick up an exhibit and 15 refer to it.</p> <p>16 A Will do.</p> <p>17 Q You also have a bag, a plastic clear bag. 18 What's contained within the plastic clear bag?</p> <p>19 A It's an exemplar TTV mesh.</p> <p>20 MR. THORNBURGH: We'll mark that as 21 Exhibit No. 6.</p> <p>22 (Exhibit 6 marked for identification.)</p> <p>23 Q (By Mr. Thornburgh) Is it just an exemplar 24 TTV?</p>
<p style="text-align: center;">Page 11</p> <p>1 either chemically or through ultraviolet radiation?</p> <p>2 A That's correct.</p> <p>3 Q Okay. And did you conduct those studies?</p> <p>4 A I did. Those studies were done at my 5 direction.</p> <p>6 Q Okay. My question was did you conduct those 7 studies, not whether or not it was done at your --</p> <p>8 A Those studies were conducted by Exponent, me 9 and some staff, as well as a third-party laboratory.</p> <p>10 Q Okay. And did you bring with you the 11 underlying data from those studies?</p> <p>12 A I did.</p> <p>13 Q Is that contained within Exhibit No. 5?</p> <p>14 A Yes, it is.</p> <p>15 Q And what underlying data do you have related 16 to those studies that were conducted at Exponent?</p> <p>17 A You have the universe of photographs and 18 images and micrographs that we took on all of the 19 tested specimens, you have a log that details each 20 specimen that was tested, and you also have the testing 21 protocols that we used at the lab.</p> <p>22 Q Okay. There's an envelope behind you.</p> <p>23 A Yes, there is.</p> <p>24 Q What's in the envelope?</p>	<p style="text-align: center;">Page 13</p> <p>1 A It is, correct.</p> <p>2 Q Did you bring invoices with you today?</p> <p>3 A I did.</p> <p>4 Q Are they also contained within the thumb 5 drive?</p> <p>6 A They are.</p> <p>7 Q And you're getting paid \$355 per hour; is 8 that correct?</p> <p>9 A Exponent is charging 355 for my time, 10 correct.</p> <p>11 Q And how much have you invoiced to the 12 defendants to date?</p> <p>13 A Through our current billing cycle, we have 14 about \$100,000 billed.</p> <p>15 Q And you say "current." Current up until what 16 date?</p> <p>17 A That would have been an invoice that would 18 have included all charges through August.</p> <p>19 Q Okay, through August. So now we're here in 20 almost October.</p> <p>21 A Yes.</p> <p>22 Q Have you done additional work since August?</p> <p>23 A We have.</p> <p>24 Q Okay. How much additional time have you</p>

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<p>1       spent either preparing for this case or for this 2       deposition?</p> <p>3       A   I don't know. That bill has not been 4       generated yet.</p> <p>5       Q   Approximately, a fair -- just give me a fair 6       estimation.</p> <p>7       A   I can give you a fair estimate of my time. 8       Probably in the order of 30 to 40 hours.</p> <p>9       Q   Okay. At 340?</p> <p>10      A   Three fifty-five.</p> <p>11      Q   Three fifty-five?</p> <p>12      A   Correct.</p> <p>13      Q   And you said you can give me a fair estimate 14     of your hours. Were there other people that were 15     involved?</p> <p>16      A   Yes.</p> <p>17      Q   How many other people were involved in the 18     work that was performed at Exponent while preparing for 19     this deposition?</p> <p>20      A   I would estimate there's been three to five 21     additional people, associate staff, working on the 22     matter. The bills will reflect the exact people and 23     their times.</p> <p>24      Q   Okay. If you turn to Exhibit No. 1 and go to</p>	<p>1       Q   And is that contained within Exhibit No. 5?</p> <p>2       A   Yes, it is.</p> <p>3       Q   Who conducted or performed the scanning 4       electron microscopy?</p> <p>5       A   Of which?</p> <p>6       Q   Of the chemical -- chemically oxidized 7       pristine exemplar and the ultraviolet radiation 8       exemplar.</p> <p>9       A   Dr. Benight did that at my direction.</p> <p>10      B-E-N-I-G-H-T.</p> <p>11      Q   And is Dr. Benight an employee of Exponent?</p> <p>12      A   She is.</p> <p>13      Q   She is. And did she maintain laboratory 14     notebooks?</p> <p>15      A   She maintained records of all her work, yes, 16     correct.</p> <p>17      Q   Did she maintain laboratory notebooks?</p> <p>18      A   I'm not sure if it's in notebook form, but 19     any -- anything that needed written down, as she 20     produced those micrographs, was written down.</p> <p>21      Q   You've written some articles or have a 22     history of analyzing -- or ensuring that good 23     laboratory practices are followed?</p> <p>24      A   What are you referencing?</p>
<p style="text-align: center;">Page 15</p> <p>1       page 4, which is the Schedule 4 -- or Schedule A, which 2       are a list of documents that were requested as part of 3       the deposition notice. A copy -- we asked for a copy 4       of your up-to-date CV. I know that there's a CV, a 5       resume, attached as an appendix to your expert report. 6       Has it been updated since you served the expert report?</p> <p>7       A   It has not.</p> <p>8       Q   And does the thumb drive, Exhibit No. 5, 9       contain your entire file?</p> <p>10      A   It does.</p> <p>11      Q   Does it contain your entire underlying data?</p> <p>12      A   It does.</p> <p>13      Q   You had indicated earlier that some of the 14     testing was outsourced to another lab.</p> <p>15      A   Correct. The histology staining was done at 16     a third-party lab.</p> <p>17      Q   Okay. And what lab was that?</p> <p>18      A   It's a lab called Histon. They are in 19     Everett, Washington.</p> <p>20      Q   Do you have the -- all of the underlying data 21     that was generated by Histon?</p> <p>22      A   Yes.</p> <p>23      Q   -- Laboratories?</p> <p>24      A   Yes, we do.</p>	<p style="text-align: center;">Page 17</p> <p>1       Q   Well, do you follow -- do you know what I 2       mean by "good laboratory practices," GLP guidelines?</p> <p>3       A   I'm sorry, I thought you were mentioning a -- 4       or referencing a specific --</p> <p>5       Q   Let me ask the question again.</p> <p>6       A   Sure.</p> <p>7       Q   Do you know what good practices are?</p> <p>8       A   Sure, yes.</p> <p>9       Q   GLP --</p> <p>10      A   Yes.</p> <p>11      Q   -- guidelines? And the GLP guidelines 12     require that laboratory notebooks are maintained, 13     correct?</p> <p>14      MR. HUTCHINSON: Object to form.</p> <p>15      THE WITNESS: They can.</p> <p>16      Q   (By Mr. Thornburgh) They do, correct?</p> <p>17      A   Depending on the nature of the work, yes, 18     they can.</p> <p>19      Q   Well, for scanning electron microscopy work?</p> <p>20      A   All of the records that were -- excuse me.</p> <p>21      All of the information that was needed to verify and 22     confirm the work that she -- that she had done on the 23     SEM has been documented.</p> <p>24      Q   She didn't maintain a GLP lab notebook,</p>

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<p>1 correct?</p> <p>2 A Without asking her, I'm not quite sure.</p> <p>3 Q So you don't know, sitting here today,</p> <p>4 whether or not she maintained a GLP notebook?</p> <p>5 MR. HUTCHINSON: Object to the form.</p> <p>6 Been asked and answered, Counsel. Move on.</p> <p>7 THE WITNESS: Same answer.</p> <p>8 Q (By Mr. Thornburgh) Did you ask her?</p> <p>9 A I don't recall if I asked her. Look, these</p> <p>10 are -- these are micrographs that have all of the</p> <p>11 information contained on the micrograph. So if there</p> <p>12 was additional notes that she took in terms of sample</p> <p>13 preparation and things like that, which would be</p> <p>14 customary, I'd expect them to be available. But we can</p> <p>15 walk through the micrographs, and I can certainly</p> <p>16 explain to you exactly everything that was done.</p> <p>17 Q In Exhibit 5, you did not produce any lab</p> <p>18 notebooks that were or may have been maintained by</p> <p>19 Dr. Benight, correct?</p> <p>20 A I would have to go back and look in the thumb</p> <p>21 drive to confirm that answer.</p> <p>22 Q Did you maintain a lab notebook?</p> <p>23 A I did not. I did not see a need to do any of</p> <p>24 that on my end.</p>	<p>1 you attended your postgraduate studies, please.</p> <p>2 A Okay. I graduated from Rensselaer</p> <p>3 Polytechnic Institute in Troy, New York as a</p> <p>4 undergraduate in mechanical engineering in 1993. I</p> <p>5 went on to pursue a master's degree in mechanical</p> <p>6 engineering and received that in 1997. I then went on</p> <p>7 to study polymer science and engineering at Rochester</p> <p>8 Institute of Technology at the master's level and</p> <p>9 graduated in 2001. And then I received my Ph.D. in</p> <p>10 material science with a focus on polymer science and</p> <p>11 engineering in 2007.</p> <p>12 Q What did you do after your education?</p> <p>13 A I guess it depends on which education</p> <p>14 component you're speaking of, but I --</p> <p>15 Q After your master's.</p> <p>16 A So let me just work you -- walk you through</p> <p>17 my employment history. So after I graduated from</p> <p>18 Rensselaer in 1993, I started working for GE Aerospace,</p> <p>19 which ultimately got divested to Lockheed Martin, in</p> <p>20 kind of a classic mechanical -- mechanical engineering</p> <p>21 aerospace world.</p> <p>22 And then from there, I went back to GE and</p> <p>23 went to GE Plastics in 1996, and I was with that</p> <p>24 company through 2011, which includes the last four</p>
<p style="text-align: center;">Page 19</p> <p>1 Q We'll get to that in greater detail in a</p> <p>2 little bit.</p> <p>3 A Uh-huh.</p> <p>4 Q You -- strike that.</p> <p>5 Request No. 16 asks for all documents or</p> <p>6 communications relating to presentations or lectures</p> <p>7 given or contributed to by you which concerned pelvic</p> <p>8 mesh, pelvic organ prolapse, or stress urinary</p> <p>9 incontinence. Do you have or have you participated in</p> <p>10 any presentations or lectures concerning pelvic mesh,</p> <p>11 pelvic organ prolapse, or stress urinary</p> <p>12 incontinence?</p> <p>13 A No.</p> <p>14 Q Did the defendants or defense counsel ask you</p> <p>15 to assume any facts in this litigation?</p> <p>16 A They did not.</p> <p>17 Q Let's look at your expert report briefly. I</p> <p>18 think it's Exhibit No. 2. Is that your full report?</p> <p>19 A Yes.</p> <p>20 Q Does it include your CV?</p> <p>21 A It does.</p> <p>22 Q You started working for -- well, strike that.</p> <p>23 Just give us a little brief background, where</p> <p>24 you went to college, where you attended your -- where</p>	<p style="text-align: center;">Page 21</p> <p>1 years of a divestiture to a company call SABIC,</p> <p>2 S-A-B-I-C. Same business, just different nameplate</p> <p>3 outside. And in 2011, I came to Exponent.</p> <p>4 Q What was your title at -- I think you said GE</p> <p>5 Aerospace. Is that correct?</p> <p>6 A I was a mechanical engineer.</p> <p>7 Q Okay. And what was your role?</p> <p>8 A I was designing, analyzing, and testing</p> <p>9 mechanical systems for defense contract work, U.S.</p> <p>10 government military work.</p> <p>11 Q And when you say "mechanical engineering and</p> <p>12 analyzing and testing mechanical systems," what do you</p> <p>13 mean by "mechanical systems"?</p> <p>14 A Large military weapons and guns, ballistic</p> <p>15 missile systems that are on Trident submarines, things</p> <p>16 of that nature.</p> <p>17 Q Okay. And when did you -- eventually you</p> <p>18 transitioned from GE Aerospace to GE Plastics?</p> <p>19 A That's correct.</p> <p>20 Q And what year was that again?</p> <p>21 A It was somewhere between 1995 and 1996.</p> <p>22 Q And what was your job title at GE Plastics?</p> <p>23 A I had several roles at GE Plastics. My</p> <p>24 entry-level job there or -- excuse me. The job that I</p>

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<p>1 first obtained when I started with that business was  2 called plastics design and analysis leader. And then I  3 held a number of increasingly -- a number of jobs with  4 increasing responsibility up until the time I left.  5 Q So plastic design and?  6 A And analysis leader.  7 Q And what did that job entail?  8 A Working with customers that were buying,  9 specifying, using our resins in all sorts of different  10 types of applications and markets.  11 Q And when did that job -- when -- did you  12 transition at some point from the plastic design and  13 analysis leader to another job at GE Plastics?  14 A I did.  15 Q And what -- when was that?  16 A That was in approximately 1998.  17 Q And what was that job title?  18 A I went on to be a senior application  19 development engineer, which is a field engineer, for  20 the company.  21 Q Senior application development engineer?  22 A That's right.  23 Q And you said it's a field engineer. What  24 does that mean?</p>	<p>1 develop standards for the plastics industry.  2 Q How long did you do that?  3 A I did variants of that job up until I left in  4 2011. The team got a little bit bigger and larger at  5 times; it became more of a global role over time. So  6 it kind of developed in size and responsibility, but it  7 was essentially the same role.  8 Q Is it fair to say that as a senior  9 application field engineer at GE Plastics, that you  10 were -- you said you were in the field. Were you  11 selling resins; is that what your job title was?  12 A No, it was not -- it was not selling resins.  13 So we had customers that were buying our resins  14 locally, and I would visit with them routinely if they  15 had failure issues, if they had technical specification  16 questions, if they wanted to know how our materials  17 could be processed in their processing equipment. So  18 that's converting raw pellets to plastics either  19 through injection molding, thermoforming, extrusion,  20 things of that nature. So it was a technical role  21 supporting our customers to help them convert our raw  22 materials into their finished molded articles.  23 Q And as the technical manager after your  24 senior application field engineering position ended,</p>
<p style="text-align: center;">Page 23</p> <p>1 A You're in the field, so you're not working in  2 an office per se, you're in the field. You have a  3 region or territory, and you're technically servicing  4 the customers in that region or territory that are  5 buying and specifying your resin.  6 Q And when did that -- you did that from 1998  7 until what year?  8 A Approximately 2001.  9 Q Okay. And what did you do from -- after  10 2001?  11 A In 2001, I became a technical manager with  12 the business.  13 Q And what did that job entail as a technical  14 manager?  15 A I was managing an engineering staff that had  16 a number of different responsibilities.  17 Q Like what?  18 A We did root cause investigations. We did  19 specification work for customers that were buying our  20 resins. We would do testing. We would look at the  21 processing of our materials in a number of different  22 applications. And we also had -- my team had a  23 regulatory agency component to it where we would  24 interface with a lot of bodies and agencies that</p>	<p style="text-align: center;">Page 25</p> <p>1 that also dealt with resins?  2 A Yes, correct.  3 Q And you were the managing -- you were  4 managing staff in that position who were determining  5 the root cause of failures of resins that GE Plastics  6 was selling?  7 A Failures of applications that used our  8 materials, correct.  9 Q What do you mean by "failures of applications  10 that used our materials"?</p> <p>11 A Well, we've got customers that are taking our  12 raw material and converting it into a plastic  13 component. Sometimes that plastic component goes out  14 to the field, it cracks, it underperforms, it doesn't  15 do what its intended use is supposed to do, and we  16 would help our customers in many instances, help them  17 understand why that material was underperforming -- or  18 why that device in our material was underperforming.  19 I failed to mention that somewhere in there,  20 I did a black-belt role. Just remembered it off the  21 top of my head. I spent two years as a black belt for  22 the company in between the field job and the technical  23 manager role.  24 Q Okay. And what does it mean to be a black</p>

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<p>1 belt?</p> <p>2 A Black belt is a title that's designated to</p> <p>3 our quality teams. It's based on the Six Sigma</p> <p>4 methodology and principles where you use statistical</p> <p>5 tools to analyze business processes and then make</p> <p>6 improvements with statistical significance.</p> <p>7 Q What types of business processes were you</p> <p>8 analyzing?</p> <p>9 A We -- a lot of different processes. Anything</p> <p>10 from manufacturing processes to improved productivity</p> <p>11 in resin manufacturing, all the way through to</p> <p>12 processes and testing that we were doing at some of our</p> <p>13 manufacturing facilities.</p> <p>14 Q If we just turn to your expert report, which</p> <p>15 is Exhibit No. 2, you have a -- after the "Limitations"</p> <p>16 page on 6, page 7, you have sort of your biography.</p> <p>17 A Correct.</p> <p>18 Q If you go to -- actually, go to page 8. It</p> <p>19 says, "Prior to joining Exponent in 2011." Do you see</p> <p>20 that, the second paragraph on page 8?</p> <p>21 A I do.</p> <p>22 Q Okay. It says that you have a variety of</p> <p>23 technical roles of increasing responsibilities.</p> <p>24 Throughout your tenure, you were routinely involved in</p>	<p>1 for IV and fluid deliveries, stopcocks, rigid fittings</p> <p>2 in fluid delivery systems, scalpels, a number of</p> <p>3 different dental applications, catheters. I think</p> <p>4 those are the ones that I recall right now.</p> <p>5 Q None of those are permanent implantable</p> <p>6 medical devices, correct?</p> <p>7 A None of them -- well, catheter, you could</p> <p>8 make an argument it has some implantation to it. And</p> <p>9 that actually was work that I did -- the one that I'm</p> <p>10 thinking of most vividly is work I did at Exponent.</p> <p>11 The other implant that I've worked on is a tongue</p> <p>12 retractor implant at Exponent.</p> <p>13 Q Okay. So you worked on a tongue retractor</p> <p>14 medical device implant. Was that a permanent medical</p> <p>15 device?</p> <p>16 A It was.</p> <p>17 Q And what's a tongue retractor?</p> <p>18 A It's basically a silicone rubber stud that</p> <p>19 gets passed through the tongue, it affixes to the floor</p> <p>20 of your oral cavity, and it prevents your tongue from</p> <p>21 falling back to your throat when you're sleeping.</p> <p>22 Q So you said tongue retractor, and what was</p> <p>23 the other permanent implantable medical device?</p> <p>24 A Catheters, catheters that go into the body</p>
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<p>1 material selection, performance, and testing for, among</p> <p>2 other things, high-demand applications, product safety</p> <p>3 assessment, and product failure analysis. As a result,</p> <p>4 you state that you have significant experience and</p> <p>5 expertise with industry standards and applicable</p> <p>6 regulations that prescribe the technical performance of</p> <p>7 polymeric materials in end-use applications, including</p> <p>8 those in the medical device industry.</p> <p>9 A That's correct.</p> <p>10 Q What medical device applications were you</p> <p>11 involved with in that 15-year period at General</p> <p>12 Electric Plastics or SABIC Innovative Plastics?</p> <p>13 A There's too many to list and remember. I can</p> <p>14 give you a snapshot of what I can remember.</p> <p>15 Q Sure. What do you remember?</p> <p>16 A First thing I remember is that selling resin</p> <p>17 into the healthcare and medical device market was a</p> <p>18 focus market for the business, so we would sell</p> <p>19 millions of pounds of material annually to applications</p> <p>20 that were servicing medical device and healthcare</p> <p>21 applications. That's first thing.</p> <p>22 Applications that I remember off the top of</p> <p>23 my head would be trocar tubes, syringes, cannulas, CPAP</p> <p>24 devices, sleep apnea masks, flexible hosing and tubing</p>	<p>1 for extended periods of time. I've worked on several</p> <p>2 of those, both on failure analysis as well as some</p> <p>3 proactive work, for some clients at Exponent.</p> <p>4 Q Neither of -- neither the tongue retractor</p> <p>5 nor the catheter would be implanted underneath the</p> <p>6 submucosa, correct? Wouldn't be implanted under the</p> <p>7 skin, correct? A catheter is inserted, right?</p> <p>8 A It goes through the skin. I mean --</p> <p>9 Q But it doesn't embed into the skin, correct?</p> <p>10 A It doesn't embed into the skin, that's</p> <p>11 correct.</p> <p>12 Q And neither does the tongue retractor,</p> <p>13 correct?</p> <p>14 A Correct. It's in the mouth.</p> <p>15 Q What medical device companies did you work</p> <p>16 with during your 15 years at General Electric Plastics?</p> <p>17 A Oh, I'm not sure I can actually give that</p> <p>18 information. That would be considered confidential.</p> <p>19 But you can be assured that it's several of the</p> <p>20 brand-name medical device companies that are out there.</p> <p>21 Q Did you work with Johnson &amp; Johnson?</p> <p>22 A I can't give you that information.</p> <p>23 Q Did you work with Ethicon?</p> <p>24 A It's the same answer. It's confidential. I</p>

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<p>1 can't tell you what specific customers we sell to.</p> <p>2 Q Did you sell any resins that were being used</p> <p>3 for permanent implantable mesh devices?</p> <p>4 A Could you repeat that?</p> <p>5 Q When you were involved in your 15 years at</p> <p>6 General Electric and SABIC, did you sell any resins to</p> <p>7 any medical devices [sic] who were using the resin to</p> <p>8 manufacture polypropylene pelvic organ mesh devices?</p> <p>9 A Not that I'm aware of. But let me just add</p> <p>10 to that that sometimes we do not have direct line of</p> <p>11 sight to where our resin ultimately ends up. And what</p> <p>12 I mean by that is we sell -- our direct sales are to</p> <p>13 molders and converters, who then sell molded parts to</p> <p>14 end-users and specifiers. So if you look at the supply</p> <p>15 chain, we don't always know where every single pellet</p> <p>16 that we manufacture ends up in the marketplace.</p> <p>17 Q You don't know one way or the other whether</p> <p>18 or not you ever worked on a resin product that was</p> <p>19 distributed or sold to a manufacturer who was using</p> <p>20 that resin to manufacture polypropylene medical</p> <p>21 devices, correct?</p> <p>22 A That's correct. I don't know for sure,</p> <p>23 correct.</p> <p>24 Q In this biography that you have, you sort of</p>	<p>1 been?</p> <p>2 A Again --</p> <p>3 Q What are specialty resins that use</p> <p>4 polypropylene as a base and then inject carbon filler,</p> <p>5 glass -- mica, glass bead, and things of that nature?</p> <p>6 A Automotive applications come to mind right</p> <p>7 away. Something that you're looking for high strength,</p> <p>8 high stiffness, good chemical resistance, those would</p> <p>9 be all the properties that that type of formulation</p> <p>10 brings to the table.</p> <p>11 Q In fact, most of your polymer science</p> <p>12 background has been with the automotive applications,</p> <p>13 correct?</p> <p>14 MR. HUTCHINSON: Object to the form.</p> <p>15 THE WITNESS: No, not true.</p> <p>16 Q (By Mr. Thornburgh) What other applications?</p> <p>17 A Again, over 20 years, too many to remember,</p> <p>18 but I'll give you a broad-brush. Fluid engineering,</p> <p>19 fluid handling, electrical devices and enclosures and</p> <p>20 components, medical, healthcare, automotive, consumer</p> <p>21 electronics, consumer devices, aerospace.</p> <p>22 Q After you left SABIC, you joined Exponent?</p> <p>23 A Correct.</p> <p>24 Q And that was in 2011?</p>
<p style="text-align: center;">Page 31</p> <p>1 generally talk or generically talk about polymers and</p> <p>2 polymeric materials, but you don't ever once reference</p> <p>3 polypropylene.</p> <p>4 A Polypropylene is a thermoplastic material</p> <p>5 that is similar or identical to the resins that we were</p> <p>6 manufacturing at GE. I can break that down if you need</p> <p>7 me to.</p> <p>8 Q Okay. So the resins that you were</p> <p>9 manufacturing at GE were not polypropylene, correct?</p> <p>10 A At the time of GE, correct. When we were --</p> <p>11 when we were purchased by SABIC in 2011, the answer is</p> <p>12 incorrect. Polypropylene was part of our portfolio.</p> <p>13 And, actually, I have to go back even further. There</p> <p>14 was an L&amp;P acquisition by GE Plastics in the mid 2000</p> <p>15 time frame, which also included polypropylene as a base</p> <p>16 resin.</p> <p>17 Q What do you mean by "base resin"? Was it a</p> <p>18 co-polymer of some sort?</p> <p>19 A It could be. In many instances, our L&amp;P</p> <p>20 business was compounding specialty resins, so you take</p> <p>21 a base polymer like polypropylene and you would</p> <p>22 incorporate carbon fillers, glass fillers, mica, glass</p> <p>23 bead, things of that nature, to enhance properties.</p> <p>24 Q For what type of application would those have</p>	<p style="text-align: center;">Page 33</p> <p>1 A That's correct.</p> <p>2 Q And you joined Exponent to help out with</p> <p>3 litigation that Exponent was hired by industry</p> <p>4 manufacturers; is that correct?</p> <p>5 A No.</p> <p>6 MR. HUTCHINSON: Object to form.</p> <p>7 THE WITNESS: No. I joined Exponent to</p> <p>8 become a consultant to polymer science</p> <p>9 engineering.</p> <p>10 MR. THORNBURGH: Go ahead and mark as</p> <p>11 Exhibit No. 7 a FAPSIG newsletter.</p> <p>12 (Exhibit 7 marked for identification.)</p> <p>13 Q (By Mr. Thornburgh) Do you know what FAPSIG</p> <p>14 is?</p> <p>15 A I do.</p> <p>16 Q What is it?</p> <p>17 A Failure Analysis and Prevention Special</p> <p>18 Interest Group.</p> <p>19 Q What's the Failure Analysis and Prevention</p> <p>20 Special Interest Group?</p> <p>21 A It's a section within the Society of Plastics</p> <p>22 Engineers.</p> <p>23 Q And is that a society that Exponent belongs</p> <p>24 to?</p>

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<p>1       A It's a society that employees from Exponent 2 belong to.</p> <p>3       Q I'll hand you Exhibit No. 7. And this is 4 dated May of 2012. Do you see that?</p> <p>5       A I do.</p> <p>6       Q If you go to the sixth page, under 7 "Announcements," do you see your picture there --</p> <p>8       A I do.</p> <p>9       Q -- at the very top?</p> <p>10      A I do.</p> <p>11      Q It says -- and right above that, it says, 12 "Exponent is pleased to announce the addition of three 13 experienced consultants to its polymer science and 14 material chemistry practice." Do you see that?</p> <p>15      MR. HUTCHINSON: Excuse me, Counsel, 16 you've given me your marked-up --</p> <p>17      MR. THORNBURGH: Oh.</p> <p>18      MR. HUTCHINSON: -- you have 19 inadvertently given me your --</p> <p>20      MR. THORNBURGH: Sorry.</p> <p>21      MR. HUTCHINSON: -- marked-up copy.</p> <p>22      Just why don't you trade out with me for the 23 one you have in your hand.</p> <p>24      MR. THORNBURGH: Sure. There you go.</p>	<p>1       litigation services for industry clients, right?</p> <p>2       A Correct.</p> <p>3       Q Like Ethicon?</p> <p>4       A Correct.</p> <p>5       Q Like Johnson &amp; Johnson?</p> <p>6       A Correct.</p> <p>7       Q Now, I've been calling you a doctor, but 8 you're not a medical doctor, correct?</p> <p>9       A That's correct.</p> <p>10      Q You're not a urogynecologist, correct?</p> <p>11      A Correct.</p> <p>12      Q You don't hold yourself out as a medical 13 doctor or an expert in medical science, correct?</p> <p>14      A Correct.</p> <p>15      Q You don't hold yourself out as a 16 urogynecologist?</p> <p>17      A Correct.</p> <p>18      Q You're not a veterinarian?</p> <p>19      A Correct.</p> <p>20      Q You're not a toxicologist?</p> <p>21      A Correct.</p> <p>22      Q And you don't hold yourself out as an expert 23 in toxicology, correct?</p> <p>24      A Correct.</p>
<p style="text-align: center;">Page 35</p> <p>1       Q (By Mr. Thornburgh) So, "Exponent is pleased 2 to announce the addition of three experienced 3 consultants in its polymer science and materials 4 chemistry practice, as well as the expansion of 5 Exponent's presence in Atlanta, Georgia and China." Do 6 you see that?</p> <p>7       A I do.</p> <p>8       Q Okay. And it says -- it's got your name 9 there. It gives a little bit of history about you. 10 And it says, "Dr. MacLean" -- that's you, right --</p> <p>11      A That's correct.</p> <p>12      Q -- "will draw from his expertise in advanced 13 high-performance thermoplastics, structure/property 14 relationships, and suitability for material selection 15 to perform litigation and nonlitigation failure 16 analyses and assist industry clients with product 17 development." Did I read that accurately?</p> <p>18      A You did.</p> <p>19      Q And does that accurately depict your role at 20 Exponent?</p> <p>21      A I'd say it depicts work that I perform at 22 Exponent, correct.</p> <p>23      Q You were hired by Exponent, in fact, 24 according to this document, to help Exponent perform</p>	<p style="text-align: center;">Page 37</p> <p>1       Q You're not a pathologist?</p> <p>2       A Correct.</p> <p>3       Q And you're not an expert in pathology or 4 histopathology analysis, correct?</p> <p>5       A Correct.</p> <p>6       Q You don't have any patents concerning 7 polypropylene medical devices, correct?</p> <p>8       A I do not.</p> <p>9       Q You're not an expert in the design of 10 polypropylene mesh devices, correct?</p> <p>11      A I have not designed a mesh device.</p> <p>12      Q You won't be offering opinions in this case 13 concerning the proper design of polypropylene mesh 14 devices, correct?</p> <p>15      MR. HUTCHINSON: Object to form.</p> <p>16      Counsel, he's already given you his opinions 17 in his expert report.</p> <p>18      MR. THORNBURGH: I get to ask the 19 questions.</p> <p>20      MR. HUTCHINSON: Sure.</p> <p>21      Q (By Mr. Thornburgh) You're not going to be 22 offering opinions concerning -- for example, you're not 23 going to offer opinions about whether the pore size in the TVT mesh is an adequate pore size, correct?</p>

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<p>1        A I'm not giving mesh design -- mesh design 2 with regards to pore size opinions. 3        Q And you're not going to offer opinions 4 concerning the -- whether or not the weight of the 5 polypropylene mesh used in the TVT is an adequate 6 weight? 7        A Correct. 8        Q You're not going to offer opinions about 9 whether or not the TVT elicits an excessive, 10 unacceptable, inflammatory response -- 11      A Correct. 12      Q -- as a design of those features, correct? 13      A That is correct. 14      Q You're not an infectious disease doctor, 15 correct? 16      A Correct. 17      Q You're not go to offer any opinions regarding 18 infection and polypropylene materials in the TVT? 19      A I am not. 20      Q Other than in this litigation, have you ever 21 consulted with a medical device manufacturer concerning 22 the design of a mesh implant? 23      A Could you repeat that one? 24      Q Other than in this litigation, have you ever</p>	<p>1        You've never analyzed explanted polypropylene 2 mesh, correct? 3        A Analyzed? No, but I've reviewed the analysis 4 of explanted meshes at length for this matter. 5        Q Let me ask a better question. 6        A Uh-huh. 7        Q Prior to this matter, prior to Butler Snow's 8 lawyers hiring you as an expert in this case, you've 9 never analyzed explanted polypropylene mesh, correct? 10      MR. HUTCHINSON: Object to form. 11      THE WITNESS: That's correct. 12      Q (By Mr. Thornburgh) Have you ever performed 13 any pre-clinical testing of polypropylene mesh implants 14 prior to this case? 15      A I have not. 16      Q You're not a pre-clinical scientist? 17      A I am not a pre-clinical scientist. 18      Q You're not going to offer opinions concerning 19 pre-clinical studies that were performed by Ethicon? 20      A If it includes biocompatibility assessment 21 that I've reviewed, it will -- it will depend on your 22 questions regarding biocompatibility. 23      Q You didn't perform any biocompatibility 24 assessments of the TVT mesh device, correct?</p>
<p style="text-align: center;">Page 39</p> <p>1 consulted with any medical device manufacturer 2 concerning the design of a polypropylene mesh implant? 3        A No, I have not. 4        Q You've never observed the implantation of 5 surgical mesh, correct? 6        A I actually have. 7        Q On video? 8        A On video. 9        Q One of Ethicon's training videos? 10      A I believe so. 11      Q Let me ask a better question. You've never 12 observed the implantation of surgical mesh devices 13 prior to your involvement in this litigation, correct? 14      A That's correct. 15      Q And this is the first case where you've ever 16 testified as an expert regarding polypropylene material 17 that was implanted in human beings? Let me ask -- 18 strike that. Let me ask a better question. 19      This is the first case where you have 20 testified as an expert regarding polypropylene material 21 that is intended to be implanted in human beings? 22      A That's correct. 23      Q Prior to your involvement -- well, strike 24 that.</p>	<p style="text-align: center;">Page 41</p> <p>1        A Correct. 2        Q So you're telling me that you may offer 3 opinions concerning the biocompatibility assessment of 4 TVT? 5        A No opinions, but we may walk through the 6 biocompatibility documents that I've reviewed. 7        Q You've never conducted any pre-clinical 8 studies yourself, right? 9        A Correct. 10      Q You've never looked at medical devices that 11 were explanted from animals -- 12      A Correct. 13      Q -- to determine whether or not it was 14 biocompatible? 15      A Correct. 16      Q Your only experience reviewing 17 biocompatibility testing has been in this case, 18 correct? 19      A No, not true. 20      Q Okay. What biocompatibility -- sorry, let 21 me -- let me ask a better question. 22      Your only experience in analyzing the 23 biocompatibility of the Prolene used in the TVT device 24 has been in this case, correct?</p>

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<p>1 A Correct.</p> <p>2 Q You've never performed any post-market</p> <p>3 testing of mesh implants prior to this case, correct?</p> <p>4 A Correct.</p> <p>5 Q Have you ever performed a failure analysis of</p> <p>6 a polypropylene mesh device prior to this litigation?</p> <p>7 A For mesh, no, but I've done scores of failure</p> <p>8 analysis with polyolefins and polypropylenes.</p> <p>9 Q What medical device have you performed a</p> <p>10 failure analysis that contained polypropylene?</p> <p>11 A Well, first of all, the market, the</p> <p>12 application doesn't matter. It's the same toolbox;</p> <p>13 it's the same tool set. If I have a -- any widget made</p> <p>14 out of polypropylene that's underperforming, cracking</p> <p>15 failing, what have you, it's the same toolbox. So it</p> <p>16 doesn't matter if it's a medical device, it doesn't</p> <p>17 matter if it's an automotive component; the same tools</p> <p>18 the same approach, the same techniques are employed</p> <p>19 Q Have you analyzed polypropylene in any</p> <p>20 application that was cracking?</p> <p>21 A I'm sure I have. I just can't recall a</p> <p>22 specific instance right now.</p> <p>23 Q You can't -- you can't identify for the court</p> <p>24 any failure analysis that you performed on</p>	<p>1 A Accelerator pedal.</p> <p>2 Q Okay. So it's a pedal used in a Toyota</p> <p>3 vehicle that was cracked?</p> <p>4 A That's correct.</p> <p>5 Q And did you perform a chemical analysis to</p> <p>6 determine if the crack was the result of oxidation or</p> <p>7 degradation? Oxidation?</p> <p>8 A No, but we certainly examined the fracture</p> <p>9 pattern, the fracture behavior, the origin of the</p> <p>10 crack, the type of material that it was.</p> <p>11 Q Okay. But you didn't perform any chemical</p> <p>12 analysis of the cracked accelerator pedal, correct?</p> <p>13 A Any chemical analysis, is that what you asked</p> <p>14 me?</p> <p>15 MR. HUTCHINSON: He did.</p> <p>16 MR. THORNBURGH: Looking for oxidation</p> <p>17 of the material.</p> <p>18 THE WITNESS: We did not specifically</p> <p>19 look for oxidation of the material.</p> <p>20 Q (By Mr. Thornburgh) Did you do FTIR</p> <p>21 analysis?</p> <p>22 A We did.</p> <p>23 Q To determine whether or not it was</p> <p>24 polypropylene?</p>
<p style="text-align: center;">Page 43</p> <p>1 polypropylene material that was cracking?</p> <p>2 MR. HUTCHINSON: Objection. Been asked</p> <p>3 and answered, Counsel.</p> <p>4 THE WITNESS: I've done so many failure</p> <p>5 analysis on cracking parts that I just need</p> <p>6 probably some time to think about that.</p> <p>7 Maybe we can -- it will come to the</p> <p>8 forefront.</p> <p>9 Q (By Mr. Thornburgh) Have you ever performed</p> <p>10 any degradation studies of failed, broken, cracked</p> <p>11 polypropylene material for any application?</p> <p>12 A Yes. Absolutely.</p> <p>13 Q Okay. And what application?</p> <p>14 A The one that now comes to mind is I actually</p> <p>15 did a -- I looked at the fractography -- the</p> <p>16 fractography and the fracture behavior of a</p> <p>17 polypropylene accelerator pedal on a Toyota vehicle.</p> <p>18 Q That's not a permanent implant, is it?</p> <p>19 A No, but it's a device made out of</p> <p>20 polypropylene.</p> <p>21 Q It's accelerated -- it's an -- it's a -- what</p> <p>22 did you say, a --</p> <p>23 A Accelerator pedal.</p> <p>24 Q Accelerator pedal?</p>	<p style="text-align: center;">Page 45</p> <p>1 A Correct. We looked at the composition, we</p> <p>2 looked for contaminants, things of that nature.</p> <p>3 Q You weren't looking for oxidation, though?</p> <p>4 A Not specifically in that matter.</p> <p>5 Q Have you ever performed a failure analysis of</p> <p>6 a polypropylene suture?</p> <p>7 A I have not, but I have certainly -- let me</p> <p>8 just go back to that.</p> <p>9 Q It's a yes or no question.</p> <p>10 MR. HUTCHINSON: Hey, Steve, you're</p> <p>11 welcome to answer his question, so go on.</p> <p>12 MR. THORNBURGH: There's not a question</p> <p>13 pending. He answered.</p> <p>14 MR. HUTCHINSON: Yeah, there is. You</p> <p>15 can answer the question, Steve.</p> <p>16 Q (By Mr. Thornburgh) You have not analyzed --</p> <p>17 MR. HUTCHINSON: Hey, Dan --</p> <p>18 Q (By Mr. Thornburgh) -- you have not</p> <p>19 performed --</p> <p>20 MR. THORNBURGH: Hold on.</p> <p>21 MR. HUTCHINSON: No, no.</p> <p>22 MR. THORNBURGH: I want to make sure he</p> <p>23 understands my question.</p> <p>24 MR. HUTCHINSON: No.</p>

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<p>1 Q (By Mr. Thornburgh) You have not 2 performed --</p> <p>3 MR. HUTCHINSON: You can answer the 4 question, Steve.</p> <p>5 Q -- a failure --</p> <p>6 MR. THORNBURGH: Hold on a second.</p> <p>7 MR. HUTCHINSON: No. Steve is trying to 8 answer your question. Steve, go on and 9 answer his question, and then Dan can follow 10 up.</p> <p>11 MR. THORNBURGH: I'm going to withdraw 12 the question. I'm going to ask it a 13 different way.</p> <p>14 Q (By Mr. Thornburgh) Prior to this case, you 15 have never performed a failure analysis of a 16 polypropylene suture, correct?</p> <p>17 A Prior to the case, I have not, but I have 18 certainly analyzed all of the data around sutures that 19 have taken -- been taken out of the body and analyzed 20 through a number of different techniques.</p> <p>21 Q As your role as a witness in this case, 22 right?</p> <p>23 A Correct.</p> <p>24 Q Well, that wasn't my question. Before you</p>	<p>1 properties of the pelvic floor, correct?</p> <p>2 A Correct.</p> <p>3 Q You're not a biologist?</p> <p>4 A I am not a biologist.</p> <p>5 Q You're not a molecular biologist?</p> <p>6 A No.</p> <p>7 Q What's -- do you know what I mean by 8 "peer-reviewed publications"?</p> <p>9 A I do.</p> <p>10 Q What does "peer-reviewed publication" mean?</p> <p>11 A Typically when a scientist writes a journal 12 article, before it gets accepted by the -- by the 13 authoritative body that governs that journal -- that 14 journal itself, your study needs to be reviewed by 15 peers and needs to be accepted by peers to make sure 16 that you have followed the scientific method prior to 17 publication.</p> <p>18 Q You've never published any articles in a 19 peer-reviewed journal concerning polypropylene mesh. 20 correct?</p> <p>21 A That is correct.</p> <p>22 Q You've never published in peer-reviewed 23 journals concerning any studies or testing that you -- 24 that you conducted concerning polypropylene</p>
<p style="text-align: center;">Page 47</p> <p>1 were hired by Butler Snow, you've never performed a 2 failure analysis of a suture device made out of 3 polypropylene?</p> <p>4 A Correct.</p> <p>5 Q Prior to this case, have you -- you've never 6 studied the biocompatibility of polypropylene mesh for 7 the human tissue, correct?</p> <p>8 A Correct, for this -- for that matter, 9 correct.</p> <p>10 Q You've never published on the subject of 11 biocompatibility of polypropylene mesh in the human 12 tissue, correct, sir?</p> <p>13 A Correct.</p> <p>14 Q Prior to being retained as an expert in this 15 case, you've never spoken or presented on the topic of 16 polypropylene mesh, correct?</p> <p>17 A Correct.</p> <p>18 Q You've never taught or lectured on the 19 subject of polypropylene mesh, correct?</p> <p>20 A I have not taught on mesh.</p> <p>21 Q You have no understanding of the 22 biomechanical properties of the pelvic floor, correct?</p> <p>23 A Could you repeat that?</p> <p>24 Q You're not an expert on the biomechanical</p>	<p style="text-align: center;">Page 49</p> <p>1 degradation, correct? And so for the record --</p> <p>2 MR. HUTCHINSON: Dan --</p> <p>3 Q -- for the record, you're --</p> <p>4 MR. HUTCHINSON: Dan -- oh.</p> <p>5 Q -- for the record, you're looking at Exhibit 6 No. 2, your publication list, correct?</p> <p>7 A That is correct. Specifically for 8 polypropylene, no, but I have done some publications 9 and presentations that look at oxidative degradation 10 mechanisms for other thermoplastic polymers.</p> <p>11 Q So the answer to my question is no, you have 12 not published any of -- testing or work that you've 13 performed analyzing degradation of polypropylene, 14 correct?</p> <p>15 MR. HUTCHINSON: Object to form.</p> <p>16 THE WITNESS: Correct. However, it's 17 the same toolbox that you use that we talked 18 about earlier.</p> <p>19 Q (By Mr. Thornburgh) Prior to this case, have 20 you ever tested polypropylene for degradation?</p> <p>21 A Oh, I'm sure I have, yes. As a matter of 22 fact, another application comes to mind now that we're 23 talking through this, yes.</p> <p>24 Q What application?</p>

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<p>1        A I have looked at the degradation and loss in  2 physical properties for a variety of different wheels  3 that are used for lawn and garden equipment. They're  4 made out of 30 percent glass-filled polypropylene.  5        Q Not isotactic, correct?  6        A No, it would be isotactic.  7        Q So 30 percent glass-filled polypropylene  8 wheels used for garden equipment, right?  9        A Lawn and garden equipment, correct.  10      Q You've never tested polypropylene medical  11 devices that have been explanted from the body looking  12 for degradation, correct?  13      A I haven't tested it myself, but I've looked  14 at a whole host of data.  15      Q In this case, right?  16      A In this case.  17      Q But prior to this case, you had never tested  18 polypropylene for degradation of medical devices that  19 were explanted from the human body?  20      A Correct. But, again, it's the same toolbox,  21 whether it was explanted or not.  22      Q You've never published in the peer-reviewed  23 literature on the subject of polypropylene, correct?  24      A No. But I would say that some of the</p>	<p>1 for the defendants or their lawyers, Butler Snow,  2 correct?  3        MR. HUTCHINSON: Object to form.  4        THE WITNESS: Can you ask that one more  5 time?  6        Q (By Mr. Thornburgh) You have only tested one  7 Prolene mesh device in your entire career, and that was  8 for the purpose of serving as an expert witness in this  9 case for the defendants or for Butler Snow, correct?  10      A Correct, but I have reviewed scores of other  11 test data that's relevant.  12      Q But that was for the purpose of this  13 litigation, correct?  14      A Correct.  15      Q You've never tested a Prolene suture prior to  16 this case, correct?  17      A Correct.  18      Q You've never tested any sutures prior to this  19 case?  20      A Prior to this case, correct.  21      Q And you -- were you retained by Butler Snow  22 or by Ethicon or Johnson &amp; Johnson?  23      A Butler Snow.  24      Q Butler Snow, it's your understanding, is</p>
<p style="text-align: center;">Page 51</p> <p>1 literature actually pertains to what I'll call sister  2 polymers.  3        Q That wasn't my question. My question was:  4 You've never published in the peer-reviewed literature  5 on the subject of polypropylene?  6        MR. HUTCHINSON: Objection. Been asked  7 and answered.  8        MR. THORNBURGH: I didn't ask about  9 sister polymers. I asked about polypropylene  10 specifically.  11      THE WITNESS: Right, but polyethylene,  12 polyphenylene ether, all of these polymers  13 have very, very similar structures. And  14 again, the approach, the tools, the analysis  15 that gets done, there's not much  16 differentiation between the two.  17      Q (By Mr. Thornburgh) Answer my question,  18 okay? You have never published in the peer-reviewed  19 literature on the subject of polypropylene  20 specifically, correct?  21      A Polypropylene specifically, that's correct.  22      Q In fact, you've only tested one Prolene mesh  23 device in your entire career, and that was for the  24 purpose of serving as an expert witness in this case</p>	<p style="text-align: center;">Page 53</p> <p>1 Johnson &amp; Johnson and Ethicon's attorneys, correct?  2        A That's my understanding.  3        Q Have you ever provided any expert witness  4 consultation or expert witness services for Butler Snow  5 in the past? Let me ask a better question.  6        Have you ever worked -- or have you ever been  7 retained as an expert or a consultant for Butler Snow?  8        A No, I don't believe so.  9        Q What law firms have retained you as an expert  10 witness?  11      A I would have to go back and look. I don't --  12      Q Just name a couple.  13      A Bowman and Brooke would be one that comes to  14 mind.  15      Q You have a list.  16      A I do.  17      Q You're looking at Exhibit -- you're looking  18 at Appendix B to Exhibit No. 2, which is a list of your  19 prior testimony; is that correct?  20      A Correct.  21      MR. HUTCHINSON: Dr. MacLean, take your  22 time.  23      THE WITNESS: Latham Watkins would be  24 another firm that has been hired -- I've been</p>

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<p>1       hired by. Lewis Thompson. Cremer Spina.  2       Norton Fulbright Rose. Those are the ones  3       that come to mind.</p> <p>4       Q (By Mr. Thornburgh) All right. And you  5       have -- in Appendix B of Exhibit No. 2, you have a list  6       of testimony that you've given in the last couple  7       years; is that correct?</p> <p>8       A    That's correct.</p> <p>9       Q    Have you given -- have you served as an  10      expert witness in more than eight cases?</p> <p>11      A    I've served as a testifying expert in eight  12      cases.</p> <p>13      Q    Have you served as an expert witness in cases  14      where you haven't provided testimony?</p> <p>15      A    Yes, there have been other cases that I've  16      been disclosed as expert -- as an expert that have  17      either settled or are still pending.</p> <p>18      Q    Okay. And so let's go through this list, and  19      then we'll talk about your work as an expert where you  20      haven't offered or provided testimony.</p> <p>21      A    Okay.</p> <p>22      Q    So in your Appendix B, you have a list of  23      cases, eight cases, where you've given testimony and  24      you have -- there's some bold letters in each case</p>	<p>1       Q    And so you were retained by the defendant in  2       that case?</p> <p>3       A    Correct.</p> <p>4       Q    And what did that case involve?</p> <p>5       A    That case involved a stuck -- excuse me --  6       stuck throttle allegation.</p> <p>7       Q    Another automotive application?</p> <p>8       A    Yes. There are polymer components throughout  9       the throttle body system, the throttle control system,  10      I should say, and the behavior of those components  11      under end-use conditions was called -- was being called  12      into question.</p> <p>13      Q    Alberto, et al. versus Toyota Motor  14      Corporation, again, you were retained by Toyota Motor  15      Corporation, a corporate defendant, regarding  16      another -- is that another stick throttle issue?</p> <p>17      A    That was an unintended acceleration. Those  18      matters were a bit different, but it was an unintended  19      acceleration matter. That was actually the one we  20      talked about earlier with the polypropylene fractured  21      accelerator pedal.</p> <p>22      Q    And you were retained by the defendant in  23      that case?</p> <p>24      A    I was. I was retained by their law firm,</p>
<p style="text-align: center;">Page 55</p> <p>1       name. Does that denote where -- which party you --  2       which party hired you to offer expert opinion  3       testimony?</p> <p>4       A    That would be the retaining -- yes, the party  5       that I was -- the beneficial party of that -- of that  6       litigation through the -- through the retainer from the  7       law firm, correct.</p> <p>8       Q    Okay. So Workhorse Custom Chassis, LLC  9       versus Robert Bosch, LLC, was that a lawsuit that was  10      brought by and against two corporations?</p> <p>11      A    Correct.</p> <p>12      Q    And what was the -- what type of expert  13      opinion testimony did you provide?</p> <p>14      A    I can tell you that that matter involved  15      phenolic pistons used in brake systems for RV vehicles  16      and the allegation was that the pistons were swelling  17      in the field over time and causing the brakes to  18      underperform in the field.</p> <p>19      Q    So that was an automotive application?</p> <p>20      A    Recreation -- yes, RV, automotive, correct.</p> <p>21      Q    And then Trice, et al. versus Toyota Motor  22      Corporation, you were retained by Toyota Motor  23      Corporation or their attorneys?</p> <p>24      A    Correct.</p>	<p style="text-align: center;">Page 57</p> <p>1       correct.</p> <p>2       Q    The law firm who was retained by the  3       defendant corporation?</p> <p>4       A    That is correct.</p> <p>5       Q    Metropolitan Property &amp; Casualty Insurance  6       versus LG Electronics, you were retained by LG  7       Electronics or their lawyers, correct?</p> <p>8       A    That's correct.</p> <p>9       Q    And again, you were an expert witness on the  10      defense side of the V, correct?</p> <p>11      A    Correct.</p> <p>12      Q    And what did that litigation involve?</p> <p>13      A    That litigation involved low-density  14      polyethylene tubing that connects the water supply  15      system from your home to the ice maker and water supply  16      system in refrigerators.</p> <p>17      Q    And you were -- the next one is Nease versus  18      Ford Motor Company. Again, you were retained by the  19      defendant or the defendant's lawyers in that  20      litigation, correct?</p> <p>21      A    That's correct.</p> <p>22      Q    And that was another automotive application,  23      a case involving some incident regarding -- some  24      failure of a Ford Motor Company vehicle, correct?</p>

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<p>1       A   Some alleged performance issues related to a 2   Ford vehicle, correct.</p> <p>3       Q   And was Nease an injured plaintiff?</p> <p>4       A   Correct.</p> <p>5       Q   And let me go back a little bit. Was Trice 6   an injured plaintiff?</p> <p>7       A   Trice was an injured plaintiff, correct.</p> <p>8       Q   And you represented the corporate defendant, 9   right?</p> <p>10      A   Through their attorney, correct.</p> <p>11      Q   Alberto, was that an injured plaintiff?</p> <p>12      A   Correct.</p> <p>13      Q   And you represented Toyota Motor Corporation 14   or their attorney, right?</p> <p>15      A   Yes.</p> <p>16      Q   Nease was another injured plaintiff and you 17   represented the defendant corporation?</p> <p>18      A   Correct.</p> <p>19      Q   Wubker, et al. versus A&amp;A Manufacturing 20   Company, what was -- what was that case about?</p> <p>21      A   That case was about a dock leveler device, an 22   airbag for the dock leveler. D-O-C-K, L-E-V-E-R -- 23   sorry. L-E-V-E-L-E-R.</p> <p>24      Q   What was the allegation in that case?</p>	<p>1       a corporate defendant, correct?</p> <p>2       A   Correct.</p> <p>3       Q   Against an injured plaintiff?</p> <p>4       A   No, no injured plaintiffs in that matter.</p> <p>5       It's a class.</p> <p>6       Q   A class of consumers who sued Ford Motor 7   Company because of some defect or alleged defect in a 8   product that Ford Motor Company sold?</p> <p>9       A   Correct, but no injured parties.</p> <p>10      Q   But you represented the corporate defendant, 11   right?</p> <p>12      A   Correct.</p> <p>13      Q   Okay. Have you ever represented an injured 14   plaintiff?</p> <p>15      A   I have not.</p> <p>16      Q   Other than these eight cases where you've 17   testified as an expert witness, how many other cases 18   have you been retained as an expert witness or 19   consultant?</p> <p>20      A   Probably on the order of 5 to 10 additional 21   matters.</p> <p>22      Q   So approximately 20 cases?</p> <p>23      A   Sounds about right.</p> <p>24      Q   All on behalf of a corporate -- well, for the</p>
<p style="text-align: center;">Page 59</p> <p>1       A   That the airbag ruptured during use and 2   injured the maintenance person that was maintaining it 3   at the time.</p> <p>4       Q   And Wubker was an injured plaintiff?</p> <p>5       A   Correct.</p> <p>6       Q   And you represented, on behalf of the 7   lawyers, A&amp;A Manufacturing Company, a corporate 8   defendant, correct?</p> <p>9       A   That is correct.</p> <p>10      Q   Promethean Insulation Technology, LLC versus 11   Reflectix Incorporated, you represented the defendant 12   corporation in that case as well, correct?</p> <p>13      A   Correct.</p> <p>14      Q   And what did that lawsuit entail --</p> <p>15      A   Those are two --</p> <p>16      Q   -- or involve?</p> <p>17      A   Those are two companies that are in 18   litigation right now regard -- revolve -- excuse me -- 19   regarding an intellectual property matter.</p> <p>20      Q   And you represented a corporate defendant in 21   that case?</p> <p>22      A   Yes, who was being sued by a corporation.</p> <p>23      Q   And Nettleton, et al. versus Ford Motor 24   Company, you again represented the Ford Motor Company,</p>	<p style="text-align: center;">Page 61</p> <p>1       vast majority of those, those were -- you were retained 2   by either a corporate defendant or their lawyers, 3   correct?</p> <p>4       A   Not in all cases, no. There are some matters 5   that are -- I'm not being -- excuse me -- I'm not 6   representing the defense in some matters.</p> <p>7       Q   So in those matters where you're not 8   representing -- or haven't been retained as a witness 9   or consultant in those matters, you were retained by a 10   corporate plaintiff?</p> <p>11      A   Correct, or a -- yeah, or a complaint -- yes, 12   correct.</p> <p>13      Q   You've always -- a hundred percent of the 14   time that you've offered your expert services has been 15   on behalf of a corporation?</p> <p>16      A   Yes.</p> <p>17      Q   And as we saw in the newsletter that we 18   looked at earlier, you were hired by -- Exhibit No. 7, 19   you were hired by Exponent to continue to offer 20   litigation services, correct?</p> <p>21      MR. HUTCHINSON: Object to form.</p> <p>22      Mischaracterizing the document. Counsel, 23   also it says clearly he was hired for other 24   things. It's a misrepresentation of the</p>

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<p>1       document.</p> <p>2       MR. THORNBURGH: That's what the</p> <p>3       document says.</p> <p>4       THE WITNESS: And litigation failure --</p> <p>5       nonlitigation failure analysis.</p> <p>6       Q (By Mr. Thornburgh) On behalf of corporate</p> <p>7       clients?</p> <p>8       A It doesn't say that.</p> <p>9       Q Well, that's what you do, right?</p> <p>10      MR. HUTCHINSON: Object to form.</p> <p>11      Argumentative.</p> <p>12      Q (By Mr. Thornburgh) You represent -- you get</p> <p>13      retained -- or Exponent gets retained and you provide</p> <p>14      services for corporate clients --</p> <p>15      MR. HUTCHINSON: Object --</p> <p>16      Q -- a hundred percent of the time?</p> <p>17      MR. HUTCHINSON: Object to form.</p> <p>18      Q (By Mr. Thornburgh) Right?</p> <p>19      MR. HUTCHINSON: Don't answer that.</p> <p>20      He's already answered that question,</p> <p>21      Counsel.</p> <p>22      MR. THORNBURGH: No, he hasn't.</p> <p>23      MR. HUTCHINSON: Yeah, he has.</p> <p>24      THE WITNESS: First of all, if you're</p>	<p>1       Q (By Mr. Thornburgh) Doctor, there are other</p> <p>2       Exponent employees who have also been retained by</p> <p>3       Ethicon and Johnson &amp; Johnson in this litigation,</p> <p>4       correct?</p> <p>5       A I believe so.</p> <p>6       Q Dr. Kevin Ong?</p> <p>7       A I -- yes, I believe he's been retained. I</p> <p>8       don't know if it's specific to this matter.</p> <p>9       Q And you're aware that Marta Villarraga and</p> <p>10      Dr. Reitman are both Exponent employees who have been</p> <p>11      retained by Johnson &amp; Johnson, Ethicon, and/or other</p> <p>12      mesh manufacturers?</p> <p>13      MR. HUTCHINSON: Object to form.</p> <p>14      THE WITNESS: I'm not aware of their</p> <p>15      involvement with Ethicon or Johnson &amp;</p> <p>16      Johnson.</p> <p>17      Q (By Mr. Thornburgh) Do you know</p> <p>18      Dr. Villarraga and Dr. Reitman?</p> <p>19      A I do.</p> <p>20      Q You are aware that they've been -- they've</p> <p>21      been retained by defendants in the mesh litigation,</p> <p>22      correct?</p> <p>23      A Correct.</p> <p>24      Q Did you communicate with them concerning this</p>
<p style="text-align: center;">Page 63</p> <p>1       asking about Exponent, the answer is no. If</p> <p>2       you're asking about me, I've already given</p> <p>3       the answer.</p> <p>4       Q (By Mr. Thornburgh) You -- as an employee of</p> <p>5       Exponent, you have been retained or offered services a</p> <p>6       hundred percent of the time for corporate clients,</p> <p>7       correct?</p> <p>8       MR. HUTCHINSON: Object to the form.</p> <p>9       Been asked and answered.</p> <p>10      THE WITNESS: Same answer.</p> <p>11      Q (By Mr. Thornburgh) Yes or no?</p> <p>12      A I answered yes already. Go back and look.</p> <p>13      Q Okay. The answer is yes, right?</p> <p>14      A Still yes.</p> <p>15      MR. THORNBURGH: Use the restroom.</p> <p>16      MR. HUTCHINSON: Okay.</p> <p>17      MR. THORNBURGH: Break.</p> <p>18      THE VIDEOGRAPHER: We are now going off</p> <p>19      the video record. The time is currently</p> <p>20      10:53. This is the end of Tape No. 1.</p> <p>21      (Recess taken.)</p> <p>22      THE VIDEOGRAPHER: We are now back on</p> <p>23      the video record with Tape No. 2. The time</p> <p>24      is currently 11:08 a.m.</p>	<p style="text-align: center;">Page 65</p> <p>1       case?</p> <p>2       A No.</p> <p>3       Q Have you talked to any experts in this</p> <p>4       litigation?</p> <p>5       A Yes.</p> <p>6       Q Who have you talked to?</p> <p>7       A I've talked to Dr. Shelby Thames.</p> <p>8       Q Any others?</p> <p>9       A No.</p> <p>10      Q And Dr. Shelby Thames is a polymer scientist?</p> <p>11      A He is.</p> <p>12      Q And he's serving as an expert polymer</p> <p>13      scientist in this case, correct?</p> <p>14      A I'm not sure. I believe he is.</p> <p>15      Q What did you talk to Shelby -- Dr. Shelby</p> <p>16      Thames about?</p> <p>17      A Polymer science.</p> <p>18      Q What about this case specifically?</p> <p>19      A We talked about a couple of different routes</p> <p>20      to get carbonyl functionality inside the IR spectra.</p> <p>21      Q A couple different roads to get carbon --</p> <p>22      A Routes, a couple of different routes.</p> <p>23      Q -- carbonyl functionality inside the IR</p> <p>24      spectra?</p>

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	Page 66	Page 68
1	A Yes.	1 THE WITNESS: I am not aware of what
2	Q What do you mean by that?	2 Dr. Thamess did in this matter.
3	A Well, I'm sure we'll get into it at some	3 Q (By Mr. Thornburgh) Did anybody -- are you
4	point, but carbonyl functionality has been seen in	4 aware of anybody that analyzed explanted TVT devices
5	several IR spectra from explants or exemplar units.	5 from any of the plaintiffs in this case?
6	And him and I were discussing the various ways that	6 MR. HUTCHINSON: Are you talking about
7	that carbonyl functionality could show up.	7 the 37 plaintiffs?
8	Q So you agree that there have been carbonyl --	8 MR. THORNBURGH: Thirty-seven
9	and by carbonyl, we're talking about groups, right, CO	9 plaintiffs.
10	bonds?	10 THE WITNESS: I am not aware of anybody
11	A Certain functional groups, correct, CO bonds.	11 that's done any work on explants from these
12	Q Which would be an -- which could be an	12 37 plaintiffs.
13	indication of oxidation or degradation through the	13 Q (By Mr. Thornburgh) Are you aware that there
14	oxidative pathway?	14 were -- there are and have been TVT explants available
15	A There are a number of different molecules	15 from plaintiffs in this case?
16	that can have carbonyl functionality in them.	16 MR. HUTCHINSON: Object to form.
17	Q One of those would be oxidation, correct?	17 Counsel, are you talking about the 37
18	A Oxidation could cause carbonyl functionality	18 plaintiffs?
19	to develop in certain polymers, correct.	19 MR. THORNBURGH: I'm talking about the
20	Q Including polypropylene, right?	20 37 plaintiffs.
21	A Yes, correct.	21 MR. HUTCHINSON: Okay.
22	Q You understand that Kevin Ong has been	22 THE WITNESS: I don't recall if I was
23	retained in this case, right?	23 made aware of that or not.
24	MR. HUTCHINSON: Object to form.	24 Q (By Mr. Thornburgh) Ethicon never came to
	Page 67	Page 69
1	THE WITNESS: I --	1 you and asked you, their polymer scientist, to analyze
2	MR. HUTCHINSON: Counsel, just for the	2 any explanted meshes for any of the women who have
3	record, Dr. Ong has not been designated as an	3 explant mesh specimens available, correct?
4	expert in this case.	4 A They did not.
5	MR. THORNBURGH: He hasn't?	5 Q Sitting here right now, you have no idea how
6	MR. HUTCHINSON: No.	6 many TTVT explant specimens are available from this
7	MR. THORNBURGH: Okay.	7 group of 37 plaintiffs, right?
8	THE WITNESS: That's -- that was why --	8 A Can you ask that again?
9	MR. THORNBURGH: I thought he had.	9 Q Sitting here right now, you have no idea how
10	MR. HUTCHINSON: Wait just a minute.	10 many TTVT explant specimens are available from this
11	No, in all fairness, he hasn't.	11 group of 37 plaintiffs, right?
12	MR. THORNBURGH: Okay.	12 A No, I don't, not without looking at some
13	MR. HUTCHINSON: Not in the Mullins	13 documents, I wouldn't be able to.
14	consolidated case.	14 Q Did you ever ask Ethicon or Ethicon's
15	MR. THORNBURGH: Okay.	15 attorneys whether any of the 37 plaintiffs had mesh
16	Q (By Mr. Thornburgh) What do you	16 explanted from their bodies?
17	understand -- well, let me ask you this question: You	17 A I did.
18	haven't analyzed any of the mesh TTVT devices that were	18 Q And what did they tell you?
19	explanted from any of the plaintiffs in this case,	19 A Yes. The answer is yes.
20	correct?	20 Q And did you say, "It might be a good idea to
21	A That's correct.	21 analyze some of those TTVT specimens to determine if
22	Q And Dr. Thamess did that, correct?	22 there's evidence of oxidation"?
23	A I --	23 A I made -- I made that request. I did not
24	MR. HUTCHINSON: Object to form.	24 receive any mesh.

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<p>1 Q So you made a request to analyze explanted  2 TTV specimens to Ethicon's attorneys, and they did not  3 provide to you any of the explanted specimens from this  4 group of 37 plaintiffs, correct?</p> <p>5 MR. HUTCHINSON: Object to form. And,  6 Counsel, if you could give us some details on  7 when these 37 explants were available, I'd  8 like to know that.</p> <p>9 MR. THORNBURGH: Well --</p> <p>10 MR. HUTCHINSON: Could you do that?</p> <p>11 MR. THORNBURGH: -- it's not my  12 deposition.</p> <p>13 MR. HUTCHINSON: Right.</p> <p>14 MR. THORNBURGH: But you know there's a  15 pathology protocol that we've been  16 following.</p> <p>17 MR. HUTCHINSON: Correct.</p> <p>18 MR. THORNBURGH: So --</p> <p>19 MR. HUTCHINSON: And if you could give  20 us some information about when these 37  21 explants were available for us to inspect, I  22 would really like to hear that.</p> <p>23 MR. THORNBURGH: It's already been done,  24 but it's not my deposition.</p>	<p>1 Q (By Mr. Thornburgh) Right?  2 A I don't recall if I was made aware of that.  3 Q And you actually asked Ethicon's lawyers if  4 you could analyze some explanted mesh from this group  5 of TTV plaintiffs, correct?</p> <p>6 MR. HUTCHINSON: Same objections. It's  7 been asked and answered, Counsel.</p> <p>8 THE WITNESS: Yeah, same answer.</p> <p>9 Q (By Mr. Thornburgh) The answer is yes,  10 right?</p> <p>11 A Correct.</p> <p>12 Q And they never provided it to you?</p> <p>13 A I did not receive any mesh.</p> <p>14 Q So you're offering opinions in this case  15 without having had the opportunity to actually do your  16 own analysis of explanted TTV mesh specimens that were  17 made available to the defense, correct?</p> <p>18 MR. HUTCHINSON: Object to form.</p> <p>19 THE WITNESS: Correct. But my scope of  20 work is a little bit different in this  21 matter. And I have certainly analyzed all of  22 the existing data that's available for the  23 last three decades on these exact TTV devices  24 or sutures or sister products. And I was</p>
<p style="text-align: center;">Page 71</p> <p>1 MR. HUTCHINSON: Okay.</p> <p>2 MR. THORNBURGH: I don't answer  3 questions under oath right now. That's his  4 job. My job is to ask the questions.</p> <p>5 MR. HUTCHINSON: So you're not going to  6 give us any information about when these 37  7 explants were available?</p> <p>8 MR. THORNBURGH: You already have -- you  9 already have the information regarding --</p> <p>10 MR. HUTCHINSON: When was it?</p> <p>11 MR. THORNBURGH: -- the availability  12 of -- I've talked to Andy Snowden about it.</p> <p>13 Q (By Mr. Thornburgh) Andy Snowden went up to  14 Toronto and participate -- are you aware that Ethicon's  15 lawyers went up to -- with Kevin -- with Dr. Ong, went  16 up to Toronto and divided some mesh specimens from this  17 group of TTV plaintiffs?</p> <p>18 A I don't -- I don't recall. I don't remember  19 if that was made -- if I was aware of that. I just  20 don't know.</p> <p>21 Q You were never made aware that Ethicon was  22 provided with half of some of the available specimens  23 from this group of TTV plaintiffs?</p> <p>24 MR. HUTCHINSON: Object to form.</p>	<p style="text-align: center;">Page 73</p> <p>1 testing some hypotheses of Dr. Iakovlev's  2 work that he didn't do in his work.</p> <p>3 Q (By Mr. Thornburgh) You said your scope is a  4 little bit different. Who determined your scope in  5 this case?</p> <p>6 A I think it was discussed between me and  7 the -- and counsel.</p> <p>8 Q And your scope didn't include actually  9 analyzing TTV specimens that were explanted from this  10 group -- from some of the women in this group of cases?</p> <p>11 A I --</p> <p>12 MR. HUTCHINSON: Same objection.</p> <p>13 THE WITNESS: I was ultimately asked to  14 look at all of the historical information  15 that was available, including all the polymer  16 science, all the general science, all the  17 testing, all the approaches, all the results  18 that have been generated, and form my own  19 opinions as to what is happening with this  20 mesh in vivo.</p> <p>21 Q (By Mr. Thornburgh) Do you know if anybody  22 analyzed mesh specimen from this group of plaintiffs?</p> <p>23 A What do you mean? Who?</p> <p>24 Q Do you know if any other expert that has been</p>

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<p>1 retained by Butler Snow has analyzed any of the mesh  2 explant TVT devices that have been removed from some of  3 these plaintiffs?</p> <p>4 A I do not know.</p> <p>5 Q Turning back to Exhibit No. 2, there's a  6 "Limitations" section. And just so the record is  7 straight, you've never looked at any mesh device in  8 this litigation that has been explanted from a woman's  9 pelvis, right?</p> <p>10 A That's been asked and answered.</p> <p>11 Q But in this -- you haven't in any -- in any  12 TVT case?</p> <p>13 A For these 37?</p> <p>14 Q In any case, ever.</p> <p>15 A Correct.</p> <p>16 Q If you turn to page 6, the limitations, it  17 says -- of Exhibit 2, it says, "At the request of  18 Butler Snow LLP, Exponent reviewed relevant scientific  19 literature, historic documented studies and expert  20 reports for the pending litigation."</p> <p>21 It doesn't say you did this. It says  22 Exponent reviewed. Who at Exponent reviewed relevant  23 scientific literature, historic documented studies and  24 expert reports in this litigation?</p>	<p>1 well, and then we discuss it.</p> <p>2 Q So you relied on your other four experts or  3 other four employees at Exponent to provide you with,  4 what, summaries of what they read?</p> <p>5 A Not -- in some cases, summaries, but in most  6 cases I would say, "Dr. Moll, please read this piece of  7 literature or these pieces of literature, and tomorrow  8 we're going to discuss them for a few hours," or,  9 "Dr. McGann, please go off and do some research on this  10 particular mode of degradation for polypropylene. I  11 will do the same. We'll come back and discuss it."</p> <p>12 That might work its way into the report, things like  13 that.</p> <p>14 Q So when you would receive summaries from some  15 of these other employees at Exponent, would they  16 provide those summaries to you in writing?</p> <p>17 A No. Typically orally.</p> <p>18 Q So you did not review all of the documents,  19 literature, depositions, and other materials that are  20 identified on -- in Appendix C of your expert report,  21 correct?</p> <p>22 A I can't tell you that I have read every  23 single page of every single document, but I can assure  24 you that I have read literally thousands of pages of</p>
<p style="text-align: center;">Page 75</p> <p>1 A First of all, I did. But the additional "we"  2 would be a few of my colleagues in the polymer science  3 practice.</p> <p>4 Q Okay, so tell me who those folks are.</p> <p>5 A Dr. Benight. Dr. Moll.</p> <p>6 Q Dr. -- how do you spell Dr. Moll's name?</p> <p>7 A M-O-L-L. Dr. Garcia. And Dr. McGann,  8 M-c-G-A-N-N.</p> <p>9 Q M-c-G-A-N-N?</p> <p>10 A Correct.</p> <p>11 Q So Dr. Benight, Dr. -- make sure I understand  12 your testimony. Dr. Benight, Dr. Moll, Dr. Garcia, and  13 Dr. McGann helped you review the scientific literature,  14 historic documented studies and expert reports in this  15 litigation?</p> <p>16 A Correct. And we do that because it's  17 important as scientists to basically do an internal  18 peer-review process. I read something, you would read  19 something, we'll debate the approach, the science, the  20 results, and come to some understanding on where we  21 agree, where we may disagree, and that's how our  22 scientific process works. So it's important that not  23 just me, but other colleagues with similar backgrounds,  24 similar levels of expertise, read the literature as</p>	<p style="text-align: center;">Page 77</p> <p>1 information on this matter.</p> <p>2 Q And you -- in addition to -- well, there's  3 two parts of Exhibit [sic] No. C. There's a list of  4 documents reviewed, and then there's a second list  5 called "Steven MacLean, Reliance List in Addition to  6 Materials Referenced in Report."</p> <p>7 A Correct.</p> <p>8 Q And so, again, you didn't review all of this  9 material either, correct?</p> <p>10 A A lot of that is duplicative. That was  11 Butler Snow bolting on to our report the -- all of the  12 information that they knew they sent us. And so my --  13 my list and my report would have those documents, plus  14 anything that we went out to the public domain, to the  15 public literature, and acquired and reviewed on our  16 own.</p> <p>17 Q Okay. And so at least for the internal  18 Ethicon documents, those were handpicked by Ethicon's  19 attorneys and provided to you, correct?</p> <p>20 A I don't know if I'd use the term  21 "handpicked." They were furnished to us from Butler  22 Snow.</p> <p>23 Q Well, you didn't go out and review their  24 database of documents on your own, correct?</p>

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<p>1       A No. But I'm sure there are occasions where I  2       said, "Hey, does XYZ document exist," or something like  3       this, and they may have gone off and looked and sent it  4       to me.</p> <p>5       Q And so you relied on Ethicon to provide you  6       with documents that Ethicon's lawyers believed was  7       relevant for the scope of your opinions in this case?</p> <p>8       A Yeah, with the two-way communication that I  9       just described.</p> <p>10      Q Can you tell me which documents or materials  11       on -- in Appendix C and the addition -- additional  12       materials that Butler Snow provided were reviewed by  13       you?</p> <p>14      A Oh, I couldn't -- I couldn't do that. That  15       would take way too much time.</p> <p>16      Q Do you know which materials were reviewed by  17       Dr. Benight, Dr. Moll --</p> <p>18      A Not specifically.</p> <p>19      Q -- Dr. Garcia?</p> <p>20      A No, not specifically.</p> <p>21      Q So you have no idea what they reviewed?</p> <p>22      A I have a general sense of what they reviewed.  23       I couldn't cite you the specific documents top to  24       bottom.</p>	<p>1       Q What's her background?</p> <p>2       A She has a chemistry background, but she also  3       has a polymers background as well.</p> <p>4       Q She's mostly a chemist?</p> <p>5       A She has a strong chemistry background,  6       correct.</p> <p>7       Q What about Dr. Moll?</p> <p>8       A Dr. Moll, she is a polymer science -- polymer  9       science and engineer -- polymer scientist and engineer.  10       She is directly on my staff.</p> <p>11       Q How about Dr. Garcia?</p> <p>12       A Dr. Garcia belongs to our  13       biomedical/biomaterials practice. That's her  14       expertise.</p> <p>15       Q You're not a biomedical --</p> <p>16       A I am not.</p> <p>17       Q -- scientist, correct?</p> <p>18       A Correct.</p> <p>19       Q And you're not a part of the biomaterials  20       practice; is that correct?</p> <p>21       A I am not. She is.</p> <p>22       Q And you're not offering opinions in this case  23       concerning the biomedical -- you're not offering  24       biomedical opinions in this -- in this case, correct?</p>
<p style="text-align: center;">Page 79</p> <p>1       Q And there's no written memorandum that would  2       identify what these other doctors at Exponent reviewed  3       and shared with you later on, correct?</p> <p>4       A Correct.</p> <p>5       Q And so you relied at least in part on the  6       conclusions and opinions reached by these other doctors  7       at Exponent, correct?</p> <p>8       A No. No. The opinions that I've formed are  9       all mine.</p> <p>10       Q You relied on their conclusions, right?</p> <p>11       A No, I didn't rely on their conclusions. I  12       had scientific discussions with them to help  13       crystallize my opinions.</p> <p>14       Q No pun intended, right?</p> <p>15       A None.</p> <p>16       Q But you can't tell me which documents or  17       materials were even reviewed by these other folks at  18       Exponent?</p> <p>19       A Not with specificity, I can't.</p> <p>20       Q Who is Dr. McBright [sic]? What's her first  21       name?</p> <p>22       A Doctor who?</p> <p>23       Q Dr. Benight. What's her first name?</p> <p>24       A Stephanie.</p>	<p style="text-align: center;">Page 81</p> <p>1       A I am not. I'm here to talk about polymers.</p> <p>2       Q Who is the fourth person? Somehow I lost my  3       list.</p> <p>4       A Dr. John McGann.</p> <p>5       Q I'm sorry, what was Dr. Garcia's first name?</p> <p>6       A Mariana. M-A-R-I-A-N-A.</p> <p>7       Q And Dr. Moll's first name?</p> <p>8       A Jericho. J-E-R-I-C-H-O.</p> <p>9       Q And Dr. John McGann, what is his background?</p> <p>10       A Similar to Stephanie's; chemistry, polymer  11       science. He's also part of our polymer science  12       practice.</p> <p>13       Q You're not a chemist, right?</p> <p>14       A I'm not a chemist. I've taken a number of  15       different chemistry classes.</p> <p>16       Q You don't hold yourself out as an expert in  17       chemistry, correct?</p> <p>18       A As an expert in chemistry? Not an expert in  19       chemistry, but I'm certainly very knowledgeable about  20       chemistry, organic chemistry, things of that nature.</p> <p>21       Q Did Stephanie Benight -- Dr. Benight,  22       Dr. Moll, Dr. Garcia, and Dr. McGann help you write  23       your expert report?</p> <p>24       A They provided some draft inputs to me.</p>

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<p>1       Q   What section did Dr. Benight write or draft?</p> <p>2       A   I don't recall specifically which section at</p> <p>3       this point. The final body of work is mine.</p> <p>4       Q   Well, she's a chemist.</p> <p>5       A   Uh-huh.</p> <p>6       Q   Did she provide some chemistry analysis in</p> <p>7       your expert report?</p> <p>8       A   I don't -- I don't specifically recall. I'm</p> <p>9       sure we had some chemistry discussions along the way.</p> <p>10      Q   What sections did Dr. Jericho Moll write or</p> <p>11      help draft?</p> <p>12      A   Jericho and I worked on the seven-year dog</p> <p>13      study section. I recall that. We worked together</p> <p>14      quite a bit on the Prolene section.</p> <p>15      Q   By "Prolene section," do you mean the Prolene</p> <p>16      microcrack section?</p> <p>17      A   I mean the section that starts on page 19</p> <p>18      that's labeled "Prolene."</p> <p>19      Q   Okay. What section did Dr. Garcia help you</p> <p>20      write?</p> <p>21      A   I'd say Dr. Garcia mostly contributed to</p> <p>22      portions of the second report, which I'll call the</p> <p>23      microscopy report.</p> <p>24      Q   And is that because Dr. Garcia was the person</p>	<p>1       Q   -- Benight, would have worked on the testing</p> <p>2       that was done in your second report and the drafting of</p> <p>3       your second report; is that correct?</p> <p>4       A   Correct. In part, correct.</p> <p>5       Q   And did any other employees of Exponent help</p> <p>6       with that regard?</p> <p>7       A   On the second report?</p> <p>8       Q   Yes.</p> <p>9       A   No, I do not believe so.</p> <p>10      Q   All right. And then Dr. Moll and you --</p> <p>11      A   Let me just rephrase that. We have an</p> <p>12      internal quality control process, so there may have</p> <p>13      been other folks beyond -- once the final draft is</p> <p>14      ready, there may have been other peer-reviewers that</p> <p>15      had provided comments or editorial changes to the</p> <p>16      document.</p> <p>17      Q   Who are those folks?</p> <p>18      A   They would be listed on the bill.</p> <p>19      Q   Are they Ph.D.s? Are they doctors?</p> <p>20      A   Typically, yes. But it's nothing more than</p> <p>21      getting a fresh set of scientific eyes on a written</p> <p>22      body of work to make sure that there's nothing that's</p> <p>23      not consistent with the scientific method or to catch</p> <p>24      potential typos and editorial issues.</p>
<p style="text-align: center;">Page 83</p> <p>1       who conducted those studies?</p> <p>2       A   Dr. Benight conducted those studies with</p> <p>3       input from Dr. Garcia.</p> <p>4       Q   And what section did Dr. McGann help you</p> <p>5       write?</p> <p>6       A   I believe I asked him to critique just some</p> <p>7       of the public literature, but I did a lot of that as</p> <p>8       well. So I think that was the extent of his work.</p> <p>9       Q   So in order for me to understand sort of who</p> <p>10      wrote which sections of the report, I'd have to look at</p> <p>11      a draft of your report?</p> <p>12      A   There's one and only one draft of this</p> <p>13      report. It's a living document. And what typically</p> <p>14      happens is, like I said, we would have a discussion,</p> <p>15      one of us might write up a paragraph or two. I have</p> <p>16      final editorial privileges of the document. I might</p> <p>17      massage it and make it my own, add my own paragraph,</p> <p>18      sections, things like that.</p> <p>19      Q   Let me make sure I understand sort of their</p> <p>20      roles a little bit more.</p> <p>21      A   Sure.</p> <p>22      Q   So Dr. Stephanie Garcia [sic] would have,</p> <p>23      with the help of Dr. --</p> <p>24      A   Benight.</p>	<p style="text-align: center;">Page 85</p> <p>1       Q   And then Dr. Jericho Moll would have worked</p> <p>2       on the seven-year dog study --</p> <p>3       A   Uh-huh.</p> <p>4       Q   -- section of your report?</p> <p>5       A   Correct.</p> <p>6       Q   And Dr. Garcia would have worked on the</p> <p>7       second report, and then John McGann would have worked</p> <p>8       on what section?</p> <p>9       A   Some -- I had him, I believe, critique some</p> <p>10      of the --</p> <p>11      Q   Critique some of the peer-reviewed</p> <p>12      publications?</p> <p>13      A   That's right. Review, synthesize, and</p> <p>14      critique.</p> <p>15      Q   So he would have worked on the section that</p> <p>16      begins where, or sections that begin where?</p> <p>17      A   Twenty-four, page 24.</p> <p>18      Q   Twenty-four through what page?</p> <p>19      A   Thirty-two.</p> <p>20      Q   And that would have been the publications</p> <p>21      concerning degradation of polypropylene, including</p> <p>22      Prolene?</p> <p>23      A   Correct.</p> <p>24      Q   Any other sections?</p>

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<p>1       A Not that I recall.</p> <p>2       Q In the "Limitations" section on page 6 of</p> <p>3     Exhibit 2, you go on to say, "Exponent investigated</p> <p>4     specific issues relevant to this report as requested by</p> <p>5     the client."</p> <p>6       What specific issues did Ethicon investigate</p> <p>7     at the request of Butler Snow, Ethicon's attorneys?</p> <p>8       MR. HUTCHINSON: Object to form.</p> <p>9       THE WITNESS: It's the same answer I</p> <p>10    gave you earlier. They asked me to review a</p> <p>11    series of historical documents and data,</p> <p>12    current expert reports, older expert reports,</p> <p>13    synthesize it, and draw my own independent</p> <p>14    conclusions on the results.</p> <p>15       Q (By Mr. Thornburgh) The paragraph goes on to</p> <p>16    say, "The scope of services performed during this</p> <p>17    investigation may not adequately address the needs of</p> <p>18    other users of this report, and any reuse of this</p> <p>19    report or its findings, conclusions, or recommendations</p> <p>20    is at the sole risk of the user."</p> <p>21       So the scope of the services performed may</p> <p>22    not adequately address the needs of other folks who may</p> <p>23    read your report and want to know a little bit of</p> <p>24    information about polypropylene degradation,</p>	<p>1     already outlined for you, and we've generated a report</p> <p>2     that summarizes that report and that addresses the</p> <p>3     specific scope of work that they asked us to do.</p> <p>4       Q You go on in the next paragraph to say, "The</p> <p>5     findings presented herein are made to a reasonable</p> <p>6     degree of engineering certainty." Did I read that</p> <p>7     correctly?</p> <p>8       A You did.</p> <p>9       Q So the scientific specialty employed by you</p> <p>10    in writing this report and reaching your opinions were</p> <p>11    of those of an engineer; is that correct?</p> <p>12       A Not solely as an engineer.</p> <p>13       Q An engineer and a --</p> <p>14       A Scientist.</p> <p>15       Q Polymer scientist?</p> <p>16       A Correct.</p> <p>17       Q You're not offering any other opinions</p> <p>18    outside the scope of engineering and polymer</p> <p>19    scientist -- science; is that correct?</p> <p>20       A And general materials science.</p> <p>21       Q What opinions are you offering as a general</p> <p>22    materials scientist?</p> <p>23       A There are materials, such as proteins, that</p> <p>24    actually are polymers, but for the sake of this</p>
<p style="text-align: center;">Page 87</p> <p>1     specifically degradation as it relates to the TTV</p> <p>2     device?</p> <p>3       MR. HUTCHINSON: Object to form.</p> <p>4       THE WITNESS: Yeah, I don't think I</p> <p>5     understand your question.</p> <p>6       Q (By Mr. Thornburgh) Well, I don't understand</p> <p>7     the sentence. So maybe you can help me understand it.</p> <p>8     It says the scope of services that you and your other</p> <p>9     colleagues performed may not adequately address the</p> <p>10    needs of other users.</p> <p>11       A Correct, so --</p> <p>12       Q What do you mean by that?</p> <p>13       A Well, the scope of the work was basically</p> <p>14    what I've already described to you, and that's exactly</p> <p>15    what Ethicon asked us to do, asked me to do, and that's</p> <p>16    the work that we did. I'm not -- I guess I'm not sure</p> <p>17    what trouble you're having understanding that.</p> <p>18       Q That it may not adequately address the needs</p> <p>19    of other users.</p> <p>20       A It may not. Another user might pick up this</p> <p>21    report and not understand it because they don't have</p> <p>22    any polymer science background, may -- and as a result,</p> <p>23    may draw erroneous conclusions from it. So all I know</p> <p>24    is that Ethicon asked me to do the work that I've</p>	<p style="text-align: center;">Page 89</p> <p>1     discussion we'll call them proteins, that are present</p> <p>2     in and around the filaments and fibers of the mesh that</p> <p>3     other scientists have characterized. And I'm relying</p> <p>4     on some of that data that I've seen. So that is why I</p> <p>5     would include proteins. The formaldehyde solution,</p> <p>6     formalin fixation solution.</p> <p>7       Q You've never conducted any of your own</p> <p>8     studies concerning the formaldehyde proteinated --</p> <p>9     protein polymer, correct, the theory of -- you're never</p> <p>10    conducted your own testing or studies concerning the</p> <p>11    theory that the cracked outer layer of the</p> <p>12    polypropylene Prolene TTV mesh fibers is a</p> <p>13    formaldehyde-protein polymer, correct?</p> <p>14       A I don't have to. That science is already</p> <p>15    founded.</p> <p>16       Q That's not my question. My question is:</p> <p>17    You've never conducted any studies --</p> <p>18       A No, but --</p> <p>19       Q -- in that regard?</p> <p>20       A -- several --</p> <p>21       MR. HUTCHINSON: Hey, one at a time.</p> <p>22       Dr. MacLean, you can finish answering the</p> <p>23    question, please.</p> <p>24       THE WITNESS: The science is well</p>

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<p>1        established, and other folks have confirmed 2        it. I've seen it in the data. It exists. 3        Q (By Mr. Thornburgh) You've never conducted 4        your own studies, correct? 5        A It would just be -- it would be redundant. 6        Correct. 7        Q You've never looked at explanted 8        polypropylene materials, period, right? 9        A Well, I've looked at plenty. I've looked at 10       plenty of micrographs. I've looked at plenty of 11       photographs -- 12       Q In this -- 13       MR. HUTCHINSON: Hold on. Dan, stop. 14       Dr. MacLean, you can finish answering the 15       question. 16       MR. THORNBURGH: In this litigation. 17       MR. HUTCHINSON: Hey, excuse me, Dan. 18       Dr. MacLean, you can finish answering his 19       question. 20       THE WITNESS: I have looked at more 21       micrographs, photographs, pictures, images of 22       so-called cracked mesh than I can count for 23       this litigation -- 24       MR. THORNBURGH: After --</p>	<p>1        throughout all of their studies. I'm referring to data 2        I believe I've seen from Dr. Jordi. And there could be 3        others. 4        Q Is Dr. Thames one of those individuals? 5        A I just don't recall. 6        Q Have you read Dr. Thames's expert reports? 7        A From the Bellew matter, I have. 8        Q And you share a lot, if not all, of the 9        opinions that Dr. Thames has expressed in those reports 10       or in his depositions, correct? 11       A I wouldn't make that characterization. I 12       have my own opinions. 13       Q You share the same opinion? 14       A No, not necessarily. I have my own opinions. 15       I'll make -- I'll let someone else make that 16       distinction. 17       Q And you say you're also relying on the public 18       literature, which has shown visual observation and 19       discussed IR data. What publications are you referring 20       to? 21       A A lot of the publications that are in my 22       expert report. Clave mentions biologic materials. I'm 23       sure Costello does. I'm sure there are others. We 24       actually see biological material on -- in Wood's work,</p>
<p>1        THE WITNESS: -- for this matter. 2        Q (By Mr. Thornburgh) Your question [sic] and 3        testimony a moment ago was, "There are materials, such 4        as protein, that actually are polymers, but for the 5        sake of this discussion we'll call them proteins, that 6        are present in and around the filaments and fibers of 7        the mesh that other scientists have characterized. And 8        I'm relying on some of that data that I've seen." 9        What data are you relying on that you suggest 10       you've seen in this statement? 11       A Visual observations that people have done, 12       the IR data that's out there that show clear evidence 13       of protein. And just reading, I've read some 14       literature about foreign body response and things of 15       that nature. So just knowing that proteins actually 16       get to the site and form. So it's really a culmination 17       of all those things, looking at the public literature, 18       looking at the historical documentation that's been 19       generated either by Ethicon or by opposing experts. 20       It's well established that proteins are present. 21       Q You say the visual observations and IR data 22       that other people have reported. Are you referring to 23       Dr. Thames? 24       A I'm referring to IR data from Ethicon</p>	<p>1        we see biologic material. You can physically see it. 2        Q That's what your -- that's what your report 3        says? 4        A That's what my report says and that's what 5        that journal article shows. 6        Q And you can see it how? 7        A You can see it in some of the 8        macro-photography in her -- in the report, in the 9        journal article. 10       Q So you think that the macro-photography of 11       the explanted polypropylene material analyzed by 12       Dr. Woods shows protein? 13       A Biological material that's most likely 14       protein or proteinaceous in nature. 15       Q Is that the section that was written by 16       Dr. McGann? 17       A Let me make it clear. The entire written 18       report is my body of work. I got draft inputs from the 19       people that I've already mentioned to you. 20       Q That's a section that was drafted by 21       Dr. McGann, right? 22       A Portions of it were. The ultimate text 23       that's in here is mine. 24       Q And so it's your opinion that the Wood</p>

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<p>1 article, scanning electron microscopy shows biologic 2 material? Is that your opinion? Is that what you're 3 saying?</p> <p>4 A Can you just let me reference something so I 5 can answer you more specifically. You're asking me 6 about a very specific micrograph. I'm trying to find 7 it.</p> <p>8 Q By "micrograph," you're talking about 9 scanning electron microscopy, right?</p> <p>10 A No, you are.</p> <p>11 MR. HUTCHINSON: Dan, hold on just a 12 minute. The doctor is trying to answer your 13 question. If you'll give him just a minute, 14 okay?</p> <p>15 THE WITNESS: It's always the last one. 16 This is what I'm referring to. Figure 1 of 17 the Wood report.</p> <p>18 Q (By Mr. Thornburgh) Figure 1 of the Wood 19 report. Which number?</p> <p>20 A Figure 1D, E, and F, those are all 21 photomicrographs of meshes, not necessarily 22 Prolene-based meshes, that were explanted and cleaned, 23 which is the most important thing. You can still 24 physically see biological material in and around the</p>	<p>1 in play.</p> <p>2 Q So my question was: You disagree with 3 Dr. Thames's opinions, an opinion that he's expressed 4 in this litigation that the Wood article in Figure 2D 5 shows degraded polypropylene?</p> <p>6 MR. HUTCHINSON: Object to form.</p> <p>7 Mischaracterizes --</p> <p>8 Q (By Mr. Thornburgh) Do you disagree with 9 that --</p> <p>10 MR. HUTCHINSON: Wait. I'm sorry. 11 Object to the form. It mischaracterizes the 12 evidence. And, Counsel, just for the record, 13 Dr. Thames has not been deposed in this 14 litigation.</p> <p>15 MR. THORNBURGH: He's been deposed in -- 16 he's been deposed in the mesh litigation 17 about the Wood article, and Dr. Thames said 18 and testified that it was his opinion that 19 the Wood article demonstrated degraded mesh 20 that degraded through the oxidative 21 pathway.</p> <p>22 THE WITNESS: That's --</p> <p>23 MR. HUTCHINSON: Hold on just a minute.</p> <p>24 MR. THORNBURGH: And --</p>
<p style="text-align: center;">Page 95</p> <p>1 mesh.</p> <p>2 Q Well, let's look at A, okay. A is the 3 cleaned -- the cleaned mesh?</p> <p>4 A It's not cleaned. That's an exemplar. It's 5 not cleaned.</p> <p>6 Q Are you telling the ladies and -- let's go 7 ahead and circle on Exhibit -- on Figure 1 -- sorry, 8 hold on one second.</p> <p>9 Are you -- have you read Dr. Thames' prior 10 depositions?</p> <p>11 A I believe I may have read portions of his 12 Bellew deposition.</p> <p>13 Q Did you talk to Dr. Thames about the Wood 14 article?</p> <p>15 A It may have come up.</p> <p>16 Q And are you aware that Dr. Thames has 17 testified in prior depositions and in other cases that 18 the Wood article actually showed degraded 19 polypropylene?</p> <p>20 A Yeah, that -- I believe that's his belief, 21 correct.</p> <p>22 Q And so you disagree with Dr. Thames?</p> <p>23 A I would say it's not conclusive enough and 24 there's evidence to show that there are other molecules</p>	<p style="text-align: center;">Page 97</p> <p>1 MR. HUTCHINSON: Wait a minute. Finish 2 your question, Dan. Are you -- are you 3 finished with your question?</p> <p>4 Q (By Mr. Thornburgh) Do you understand that 5 he's testified to that in prior cases?</p> <p>6 MR. HUTCHINSON: Okay, hold on just a 7 minute. Object to form. Also 8 mischaracterizes testimony.</p> <p>9 Dan, if you have a copy of Dr. Thames' 10 transcript, we'd like to see it. Do you have 11 a copy?</p> <p>12 Q (By Mr. Thornburgh) Do you -- do you 13 understand that's his opinion, yes or no?</p> <p>14 MR. HUTCHINSON: Dan, do you have a copy 15 of Dr. Thames' transcript?</p> <p>16 MR. THORNBURGH: I do.</p> <p>17 MR. HUTCHINSON: Okay. Can we see it, 18 please?</p> <p>19 MR. THORNBURGH: Well, I'm not going to 20 look for it right now, but we'll look at it 21 later on.</p> <p>22 THE WITNESS: What's your question?</p> <p>23 Q (By Mr. Thornburgh) Let's assume that 24 Dr. Thames testified that the Wood article, the</p>

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<p>1 polypropylene material explanted in the Wood article  2 and analyzed, showed evidence of oxidatively degraded  3 polypropylene. Would you disagree with that opinion?  4       MR. HUTCHINSON: Same objections.  5       THE WITNESS: This is how I will answer  6 it. There's a carbonyl peak present that he  7 looks at and believes it's an indication of  8 polypropylene oxidation. However, there are  9 other peaks when I look at the PTFE mesh,  10 when I look at the PET mesh, and I look at  11 their IR spectra, there are other  12 accounted-for peaks that might suggest  13 something other than oxidation is going on.  14 Q (By Mr. Thornburgh) I'm talking about the  15 polypropylene.  16 A I understand what you're --  17 Q I'm not talking about --  18 A -- talking about.  19 Q -- PET or -- PET or PTFE.  20 A I understand what you're talking about. I'm  21 telling you that if you look at the data in its  22 totality and you look at some of the other peaks that  23 have actually worked their way into the other  24 materials -- and by the way, those peaks gets masked in</p>	<p>1 degradation, right?  2       A I'm saying that the carbonyl functionality,  3 it's just that, it's carbonyl functionality. That is a  4 ubiquitous molecule in organic molecules -- sorry, it's  5 a ubiquitous functional group within organic molecules.  6 And you can't look at the carbonyl peak at 1740, 1720,  7 wherever it is, and just say it's oxidation. It's not  8 definitive enough.  9       When you look at the in vivo environments  10 coupled with -- and we're not even talking about  11 Prolene, by the way, in this -- that needs to be on the  12 record. There's nothing that suggests or even confirms  13 that Prolene was part of the Wood study. So let's get  14 that on the table. But just in general, if you look at  15 the material composition of Prolene and if you look at  16 the in vivo environments of this -- of this mesh, there  17 are way too many molecules present that have carbonyl  18 functionality to simply go ahead and look at that peak  19 and assign it to oxidation. You just can't do that.  20 It's scientifically unsound.  21 Q Well, why don't you look at the Wood  22 article -- just so the record is clear, the Wood  23 article was published in 2013, right? Why don't we  24 just go ahead and mark it as Exhibit No. 8 since we're</p>
<p style="text-align: center;">Page 99</p> <p>1 the polypropylene material because they already have  2 functional groups at 2800, 2900. So if you look at all  3 that data in its totality, you could make the argument  4 that, yes, it might be oxidation, but it also could be  5 some sort of plasticizer, natural plasticizer in the  6 body, that has a carbonyl-containing functional group.  7       Q So let me just understand your opinion here.  8       A Sure.  9       Q If Dr. Thames has testified that this was  10 degraded, oxidatively degraded polypropylene, you would  11 disagree with his opinion?  12       MR. HUTCHINSON: Object to form. Asked  13 and answered, Counsel. He just explained to  14 you his opinion about that.  15       THE WITNESS: It's not a yes or no  16 answer. I don't disagree with him. I'm  17 saying that there could be another reason why  18 that carbonyl peak has shown up in that  19 range.  20       Q (By Mr. Thornburgh) Okay. So then let me --  21 entertain me for a moment.  22       A Sure.  23       Q In the Wood article, you would agree that the  24 polypropylene material analyzed could be oxidative</p>	<p style="text-align: center;">Page 101</p> <p>1 talking about it. We kind of jumped to it, but might  2 as well talk about it and mark it.  3       MR. HUTCHINSON: You got a copy?  4       (Exhibit 8 marked for identification.)  5       Q (By Mr. Thornburgh) Okay. And you  6 understand that the -- Wood and her colleagues analyzed  7 explanted polypropylene, PTFE, and PET hernia meshes  8 from individual plaintiffs -- patients, right?  9       A I do. Well, no, it's -- I believe it's one  10 patient.  11       Q From an individual patient?  12       A Correct.  13       Q Okay. And if you turn to the -- if you look  14 at the abstract, first of all, it says, "Synthetic mesh  15 materials are exposed to foreign body responses, which  16 can alter physicochemical properties of the material."  17 Did I read that accurately?  18       A You did.  19       Q And then it goes on and says that three mesh  20 materials, including a polypropylene mesh, was analyzed  21 from a single patient, and the results from infrared  22 spectroscopy demonstrated significant oxidation of the  23 polypropylene mesh, while ePTFE and PET showed slight  24 chemical changes that may be caused by adherent scar</p>

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<p>1 tissue. Differential scanning calorimetry results  2 showed a significant decrease in the heat of  3 enthalpy -- enthalpy -- did I pronounce that  4 correctly --  5 A You did.  6 Q -- and melt temperature in the polypropylene  7 mesh.  8 Okay, so just from looking at the abstract,  9 we're going to dig in a little bit deeper --  10 A Uh-huh.  11 Q -- but the scientist here performed a number  12 of different testing to determine whether or not there  13 was evidence of oxidative degradation of the  14 polypropylene material and the other mesh materials as  15 well, right?  16 A Correct.  17 Q One of those was scanning electron  18 microscopy, right?  19 A Correct, which tells you nothing about  20 oxidation.  21 Q That wasn't my question. One of the studies  22 they did was scanning electron microscopy, correct?  23 MR. HUTCHINSON: He answered, Counsel.  24 THE WITNESS: Yes.</p>	<p>1 energy required to break up the crystals in the  2 crystalline material.  3 Q So with that -- so for oxidized  4 polypropylene, you'd have a decrease in the heat of  5 enthalpy, which would indicate that there are more  6 amorphous regions on the material; is that fair?  7 A Correct, you might get more amorphous  8 regions.  9 Q And amorphous regions are regions of a  10 polymer which are more susceptible to oxidation or are  11 oxidized?  12 A They can be more susceptible to oxidation  13 than the -- than the crystalline domains, correct.  14 Q And melt temperature is another test that can  15 be conducted, right?  16 A Sure.  17 Q And if there's a drop in the melting point of  18 a polypropylene or polymer material, that's also an  19 indication of oxidized polypropylene, correct?  20 A Not necessarily.  21 Q But if you take a pure polypropylene sample  22 and you oxidize it and it degrades and you do  23 melt-point temperature and it drops, that's clearly  24 oxidized polypropylene?</p>
<p style="text-align: center;">Page 103</p> <p>1 Q (By Mr. Thornburgh) They also did FTIR,  2 right?  3 A Right.  4 Q And FTIR looks at what?  5 A Functional groups within a certain molecule.  6 Q Okay. So polypropylene will have a  7 fingerprint?  8 A Correct.  9 Q And degraded polypropylene will have carbonyl  10 functional groups, correct?  11 A Oxidized polypropylene --  12 Q Oxidized polypropylene will have a carbonyl  13 functional group or groups, correct?  14 A It can.  15 Q And where do those carbonyl groups fall  16 within the FTIR spectra of oxidized polypropylene?  17 A It can range anywhere from the high 1600s to  18 the high 1700s.  19 Q And they also performed differential scanning  20 calorimetry, right?  21 A Correct.  22 Q Which showed a decrease in the heat of  23 enthalpy. What does that mean?  24 A The amount of crystallinity -- the amount of</p>	<p style="text-align: center;">Page 105</p> <p>1 A No. No, it's not clearly. That is one  2 explanation. The most likely explanation is that you  3 have aliphatic ester compounds, which Dr. Jordi told us  4 in Bellew come -- are actually inside the polypropylene  5 filaments. They plasticize the material, and that is  6 why you get a reduction in the melt temperature.  7 Q I wasn't -- I -- you must have misunderstood  8 me.  9 A I don't think I did.  10 Q Intentionally oxidized pristine material,  11 okay? If you take -- if you intentionally oxidize  12 pristine material that's never been in a biological  13 environment --  14 A Okay, sure.  15 Q -- and you get a FTIR score between 1600 and  16 1700s, that would be -- you could say that would be  17 oxidative degradation or evidence of oxidative  18 degradation, correct?  19 MR. HUTCHINSON: Object to form,  20 Counsel. Are you talking about materials or  21 you're talking about Prolene?  22 MR. THORNBURGH: Talking about  23 polypropylene mesh, pristine --  24 intentionally --</p>

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<p>1           MR. HUTCHINSON: Polypropylene --</p> <p>2           MR. THORNBURGH: Yep.</p> <p>3           MR. HUTCHINSON: I'm sorry. Tell us for</p> <p>4           the record what you're talking about.</p> <p>5           MR. THORNBURGH: Pristine polypropylene</p> <p>6           mesh --</p> <p>7           MR. HUTCHINSON: Okay.</p> <p>8           MR. THORNBURGH: -- that is</p> <p>9           intentionally oxidized.</p> <p>10          THE WITNESS: Sure. As long as -- we</p> <p>11          can continue to have this debate as long as</p> <p>12          it's understood we're not talking about</p> <p>13          Prolene for -- you said polypropylene.</p> <p>14          That's what the Wood article talks about.</p> <p>15          MR. THORNBURGH: I understand. You've</p> <p>16          been hired and you're being paid by Ethicon</p> <p>17          to defend its --</p> <p>18          THE WITNESS: No, I'm telling you there</p> <p>19          is a --</p> <p>20          MR. HUTCHINSON: I'm sorry, guys. Y'all</p> <p>21          need to -- one at a time. Dr. MacLean, you</p> <p>22          can go on.</p> <p>23          THE WITNESS: I'm telling you there is a</p> <p>24          scientific difference, a significant</p>	<p>1           THE WITNESS: Let's do it.</p> <p>2           Q (By Mr. Thornburgh) All right. So let's</p> <p>3           assume that you have a pristine polypropylene, Bard's</p> <p>4           material.</p> <p>5           A We'll just call --</p> <p>6           Q Does that make you feel better?</p> <p>7           A No.</p> <p>8           Q Or is that one of your clients?</p> <p>9           A No, neither.</p> <p>10          MR. HUTCHINSON: Hold on just a minute.</p> <p>11          Hey, Dan, excuse me --</p> <p>12          MR. THORNBURGH: Hold on. Let me just</p> <p>13          run him through this.</p> <p>14          MR. HUTCHINSON: No. Stop. No, we're</p> <p>15          not going to go forward like that if you keep</p> <p>16          up that line of questioning. Do you</p> <p>17          understand me?</p> <p>18          MR. THORNBURGH: Let's --</p> <p>19          MR. HUTCHINSON: Dan, do you understand?</p> <p>20          MR. THORNBURGH: Let's do a different</p> <p>21          hypothetical.</p> <p>22          MR. HUTCHINSON: All right. Is that</p> <p>23          question withdrawn?</p> <p>24          Q (By Mr. Thornburgh) Polypropylene</p>
<p style="text-align: center;">Page 107</p> <p>1           scientific difference between Prolene and</p> <p>2           polypropylene. That's what I'm telling you.</p> <p>3           And the Wood article is square on that. It's</p> <p>4           polypropylene, not Prolene.</p> <p>5           MR. THORNBURGH: We're going to look at</p> <p>6           all of the evidence --</p> <p>7           THE WITNESS: Sure.</p> <p>8           MR. THORNBURGH: -- okay? Because you</p> <p>9           have to look at the totality of the evidence,</p> <p>10           right?</p> <p>11          THE WITNESS: Right. I'm just saying</p> <p>12          you have to be clear about the material</p> <p>13          you're talking about because if you put -- if</p> <p>14          you put Prolene in an oxidized environment</p> <p>15          and you put polypropylene in an oxidized</p> <p>16          environment, I'm not sure we're going to</p> <p>17          agree on some of the things that you're just</p> <p>18          about to say, so we just need to be clear.</p> <p>19          MR. THORNBURGH: We're going to look at</p> <p>20          the totality of the evidence; we're going</p> <p>21          to --</p> <p>22          THE WITNESS: Let's do it.</p> <p>23          MR. THORNBURGH: -- explore it</p> <p>24          together.</p>	<p style="text-align: center;">Page 109</p> <p>1           material manufactured by --</p> <p>2           MR. HUTCHINSON: Dan, is that question</p> <p>3           withdrawn?</p> <p>4           MR. THORNBURGH: No.</p> <p>5           MR. HUTCHINSON: All right, well --</p> <p>6           Q (By Mr. Thornburgh) Polypropylene material</p> <p>7           manufactured by Company X.</p> <p>8           A We can just call it polypropylene material.</p> <p>9           Why don't we just call it neat, N-E-A-T, polypropylene.</p> <p>10          Q Neat polypropylene --</p> <p>11          A Good.</p> <p>12          Q -- intentionally oxidized.</p> <p>13          A Let's do it.</p> <p>14          Q You're going to find a -- carbonyl functional</p> <p>15          groups within the -- according to you, the range of</p> <p>16          1600 to 1700s, correct?</p> <p>17          A Yeah, 1650 to high 1700s, correct.</p> <p>18          Q All right. And if there's a drop in the heat</p> <p>19          of enthalpy, that's additional evidence of oxidized</p> <p>20          polypropylene, correct?</p> <p>21          A I think it would be --</p> <p>22          Q Amorphous?</p> <p>23          A It would be evidence that you had some</p> <p>24          degradation of the polymer chains.</p>

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<p>1       Q    Okay. And if you have a drop in the melt 2    temperature, that's also evidence of or some evidence 3    of oxidatively degraded polypropylene, correct? 4       A    In that scenario, it would track. 5       Q    And in this case, the Wood case, they 6    performed all those studies and they found evidence 7    of -- in fact, they report the results of infrared 8    spectroscopy -- that's FTIR that we've been talking 9    about, right -- 10      A    Correct. 11      Q    -- demonstrated significant oxidation, right? 12      A    That's their words, correct. 13      Q    And additional studies, a differential 14    scanning calorimetry, showed significant decrease in 15    heat of enthalpy and melt temperature, right? 16      A    Correct. 17      Q    And so that would be indication or evidence 18    of oxidized polypropylene, right? 19      A    It is. That set of facts is consistent with 20    oxidation. That set of facts is also consistent with 21    other molecules that may be diffusing into the polymer. 22      Q    And so if you turn the page -- turn the page. 23      A    Okay. 24      Q    Okay.</p>	<p>1       body of literature concerning complications from 2    polypropylene meshes, have you? 3            MR. HUTCHINSON: Object to form. 4            THE WITNESS: I can't say I've looked at 5    the entire body of literature, correct, on 6    that specific -- on that specific subject. 7            Q (By Mr. Thornburgh) In fact, you focused 8    on -- just on polymer science, basically? 9            A    Primarily, but I definitely looked at 10    other -- I'll call them auxiliary topics related to 11    this matter. I looked at some public literature that 12    should be in my files. 13           Q    And do you understand the difference between 14    a clean contaminated area and a -- and a clean surgical 15    site? 16      A    Generally speaking, yes. 17      Q    What's your understanding of the two? 18      A    Repeat the question. 19           Q    Do you understand what the difference is of 20    a -- well, let me ask you this: The surgical site of 21    the vagina, what type of environment is that? Is it 22    aseptic, is it septic, is it clean, is it clean 23    contaminated -- 24           MR. HUTCHINSON: I'm going to -- hold on</p>
Page 111	Page 113
<p>1       A    To which page? 2       Q    The next page in the -- in the study. At the 3    very top, it says, "Since the mid-nineties, the most 4    common method of repairing abdominal hernias has been 5    the tension-free repair using a variety of synthetic 6    mesh such as polyethylene, heavy weight polypropylene, 7    expanded polytetrafluoroethylene," and so on and so 8    forth. And it goes on to say, "A large" -- down 9    after -- 10      A    I'm with you. 11      Q    -- Footnote 4 -- "A large subset of 12    recurrence surgeries may be due to the lack of mesh 13    inertness in vivo. These materials result in a large 14    foreign body response that some thought was necessary 15    to repair the defect. In recent years, there has been 16    new evidence that a large foreign body response can 17    result in physicochemical changes in the mesh material, 18    which may lead to poor patient outcomes and 19    recurrences. While synthetic mesh" -- let me just stop 20    there for a minute. 21           You haven't gone out and looked at the entire 22    body of literature concerning polypropylene -- strike 23    that. 24      You haven't gone and looked at the entire</p>	<p>1       just a minute. 2           Q    -- is it contaminated? 3            MR. HUTCHINSON: I'm going to object to 4    the extent it's outside his expert report. 5            MR. THORNBURGH: Okay. 6            Q (By Mr. Thornburgh) You're not going to 7    offer any opinions about that, are you? 8      A    I'm not. 9           Q    You didn't read any publications or 10    literature concerning the different surgical site 11    environments concerning contamination versus 12    noncontaminated implant products, correct? 13           A    I may have read something along those lines 14    along the way. They did not come into my opinions. 15           Q    So you didn't -- you haven't considered those 16    medical issues in forming your opinion in this case; is 17    that fair? 18           MR. HUTCHINSON: Object to form. 19           THE WITNESS: Can you repeat that 20    question? 21           Q (By Mr. Thornburgh) Yeah. My question 22    originally was... 23           (Discussion off the written record.) 24           Q (By Mr. Thornburgh) My question was: You</p>

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<p>1 didn't read any publications or literature concerning 2 the different surgical site environments and the role 3 that those environments play in implantable mesh 4 devices?</p> <p>5 A And I'd say my answer is, yes, I've read some 6 literature along the way, but they did not -- they have 7 not really -- they have not influenced my opinions.</p> <p>8 Q Right. You read those, but you didn't 9 consider those -- the differences or those publications 10 that discuss the impact of the surgical site on the 11 biomechanical properties of mesh devices, correct?</p> <p>12 A I'm not sure what you mean by the word 13 "consider." But I would say that they were certainly 14 part of my institutional knowledge that I built up as I 15 read through all of the literature.</p> <p>16 Q Well, what is the significance of the 17 environment in which a polypropylene material will be 18 implanted? What's the difference between a clean 19 contaminated versus contaminated field?</p> <p>20 A Here's how I'll answer that to you. Here's 21 how I'll answer that for you. There are a number of 22 different molecules within the body -- lipids, esters, 23 cholesterols, things of that nature -- that have a very 24 specific chemical signature to them, chemical structure</p>	<p>1 resulting in groin pain and prolapse."</p> <p>2 Did I read that accurately? Do you know 3 where I'm at?</p> <p>4 A I just -- I just caught up with you. Just 5 tell -- just point to me on my document where you 6 started reading from.</p> <p>7 Q Right here (indicating) to right there 8 (indicating). It says -- so let's just make sure we're 9 on the same page. "While synthetic mesh is frequently 10 utilized to repair hernias, these materials are also 11 being utilized as pelvic slings for urogynecologic 12 applications. Unfortunately, these mesh materials, 13 also composed of polypropylene, PET, and ePTFE, are 14 experiencing biocompatibility problems which are 15 resulting in groin pain and prolapse."</p> <p>16 A That's what it says.</p> <p>17 Q Okay. And you didn't read -- you weren't 18 focused on the biocompatibility problems which were 19 causing groin pain and prolapse in patients who were 20 implanted with polypropylene mesh devices for 21 urogynecologic applications, correct?</p> <p>22 MR. HUTCHINSON: Object to form.</p> <p>23 THE WITNESS: No, because I'm not aware 24 of any biocompatibility issues associated</p>
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<p>1 to them, which includes carbonyl formation -- or 2 carbonyl functionality, rather. They have the ability, 3 and Jordi has proven this, have the ability to diffuse 4 into the filaments and cause a plasticizing effect. 5 And all I'm saying is that mechanism has been proven to 6 exist and there are -- there's direct results from that 7 mechanism taking place.</p> <p>8 Q Have you looked at any studies that 9 differentiated between the biomechanical properties of 10 implantable surgical devices of a clean surgical field 11 versus a clean contaminated surgical field?</p> <p>12 A I don't recall.</p> <p>13 Q Did you consider that issue in rendering your 14 opinions in this case?</p> <p>15 A I don't believe that they came into my 16 opinions.</p> <p>17 Q It goes on -- if you look at the same page, 18 page 1122 of the -- of Exhibit 8, 1122 of Exhibit 8, it 19 goes on and says, "While synthetic mesh is frequently 20 utilized to repair hernias, these materials are also 21 being utilized in pelvic slings for urogynecologic 22 applications. Unfortunately, these mesh materials, 23 also composed of polypropylene, PET, and ePTFE, are 24 experiencing biocompatibility problems which are</p>	<p>1 with Prolene.</p> <p>2 Q (By Mr. Thornburgh) You're not aware of an 3 biocompatibility --</p> <p>4 A Biocompatibility issues associated with 5 Prolene.</p> <p>6 Q So you didn't -- you didn't seek out those 7 publications?</p> <p>8 MR. HUTCHINSON: Object to form.</p> <p>9 Mischaracterizes his testimony.</p> <p>10 THE WITNESS: The record is clear that 11 the Prolene material has been biocompatible 12 since 1969.</p> <p>13 Q (By Mr. Thornburgh) Do you know how many 14 women have sued the client that you work for right now?</p> <p>15 A No idea.</p> <p>16 Q Do you know what complications rate for 17 pelvic organ prolapse have been -- sorry, strike that. 18 Do you know what Ethicon's own internal 19 scientists have found?</p> <p>20 A Regarding?</p> <p>21 Q Strike that.</p> <p>22 Do you know what Ethicon's key opinion 23 leaders have found or have you considered the 24 publications by Ethicon's key opinion leaders</p>

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<p>1 concerning complications associated with Prolene pelvic 2 organ prolapse devices?</p> <p>3 MR. HUTCHINSON: Object to form.</p> <p>4 THE WITNESS: No, my work is not focused 5 on any of those so-called or alleged 6 complications.</p> <p>7 Q (By Mr. Thornburgh) You didn't -- you didn't 8 read all of the publications that discuss that, right?</p> <p>9 MR. HUTCHINSON: Object to form.</p> <p>10 Q (By Mr. Thornburgh) That wasn't your focus?</p> <p>11 A That --</p> <p>12 Q Your focus wasn't --</p> <p>13 MR. HUTCHINSON: Excuse me. One at a 14 time. Dr. MacLean, you can finish answering 15 the question.</p> <p>16 THE WITNESS: That was not within my 17 scope of work.</p> <p>18 Q (By Mr. Thornburgh) So you are not offering 19 opinions concerning the complication rates or the 20 biocompatibility issues of Prolene mesh devices, 21 correct?</p> <p>22 A Again, I'm not aware of any biocompatibility 23 issues. And, no, I'm not offering any opinions about 24 any type of complication rate.</p>	<p>1 MR. HUTCHINSON: You're saying 122 and 2 it's not 122. It's 114 [sic].</p> <p>3 MR. THORNBURGH: I'm sorry. 1114. I 4 was looking at the wrong side.</p> <p>5 MR. HUTCHINSON: That's fine.</p> <p>6 MR. THORNBURGH: 1114.</p> <p>7 MR. HUTCHINSON: That's fine.</p> <p>8 Q (By Mr. Thornburgh) See where it says, "On 9 July 13th, 2011, the FDA issued a statement warning 10 surgeons and patients about the complications 11 associated with surgical mesh"? Did you read the FDA 12 warnings?</p> <p>13 A Which warnings?</p> <p>14 Q Did you read the FDA statement warning 15 surgeons and patients about complications associated 16 with surgical mesh?</p> <p>17 A No, I did not.</p> <p>18 Q Because you keep on saying, "I'm not aware of 19 any biocompatibility issues."</p> <p>20 A Correct.</p> <p>21 MR. HUTCHINSON: Hold on just a minute. 22 I'm sorry, is that a question?</p> <p>23 MR. THORNBURGH: Yeah.</p> <p>24 Q (By Mr. Thornburgh) So -- but you --</p>
<p style="text-align: center;">Page 119</p> <p>1 Q Are you aware that -- if you go on to the 2 next sentence -- we're not done yet -- on July 13th, 3 2011, the FDA issued a statement warning surgeons and 4 patients about the complications associated with 5 surgical meshes?</p> <p>6 MR. HUTCHINSON: Excuse me, Dan. What 7 page are you on?</p> <p>8 MR. THORNBURGH: Same page, just --</p> <p>9 MR. HUTCHINSON: One twenty?</p> <p>10 MR. THORNBURGH: One twenty-two [sic] of 11 Exhibit -- page -- the very top right-hand 12 corner says 122 [sic] of Exhibit No. 8, and 13 we're halfway through the left column all the 14 way down.</p> <p>15 MR. HUTCHINSON: I'm sorry, but that's 16 page --</p> <p>17 MR. THORNBURGH: I might have a 18 different page number.</p> <p>19 MR. HUTCHINSON: So the document -- I 20 think you're reading from page 114 [sic].</p> <p>21 MR. THORNBURGH: Just the second page of 22 the -- the second page of Exhibit 8.</p> <p>23 MR. HUTCHINSON: Okay. You're saying --</p> <p>24 MR. THORNBURGH: Left-hand column.</p>	<p style="text-align: center;">Page 121</p> <p>1 MR. HUTCHINSON: All right. I'm sorry. 2 Just, Dan, if you could phrase your comment 3 to a question, that would be helpful.</p> <p>4 Q (By Mr. Thornburgh) So you aren't aware of 5 the -- strike that.</p> <p>6 It goes on to say, "More recently, the FDA is 7 considering reclassifying urogynecologic surgical mesh 8 used to repair pelvic organ prolapse from Class II to 9 Class III." Do you see that?</p> <p>10 A I do.</p> <p>11 Q "Synthetic meshes are recognized as foreign 12 bodies and thus are subjected to various enzymatic 13 attacks by the body."</p> <p>14 Do you know what they mean by "enzymatic 15 attacks by the body"?</p> <p>16 A I do. That's part of the foreign body 17 response when the implant goes inside the body.</p> <p>18 Q What is -- what is -- what is the foreign 19 body response to the implantable foreign object? 20 Strike that.</p> <p>21 How does the body respond to the foreign 22 body?</p> <p>23 A Okay. Look, this is not my area of 24 expertise, but I'll tell you what I've learned through</p>

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<p>1 reading the literature, that once you put the implant  2 inside the body, proteins arrive at the site, enzymes  3 arrive at the site, macrophages arrive at the site,  4 foreign body giant cells actually get developed over  5 time that ultimately turns into scar tissue and  6 collagen and forms a network of tissue that embraces  7 the mesh within the existing -- within the existing  8 surrounding tissue.</p> <p>9 Q Do you know what frustrated phagocytosis is?</p> <p>10 A I read the term. I just can't recall what it  11 means at this moment.</p> <p>12 Q The immune response to the foreign body is to  13 try to get rid of it, right?</p> <p>14 A That's the foreign body response of the body,  15 correct, of the human body.</p> <p>16 Q And it does that by sending in its troops,  17 right, it sends in macrophage --</p> <p>18 A Yeah, all the things that I just described.</p> <p>19 Q Giant cell multinucleated foreign body --</p> <p>20 A Generally speaking, yes.</p> <p>21 Q Uh-huh. And there are chemicals that are --  22 that are produced during this immunologic response to  23 the foreign body, the mesh, correct?</p> <p>24 A Correct.</p>	<p>1 THE WITNESS: Can you just repeat that  2 last question?</p> <p>3 Q (By Mr. Thornburgh) Well, I said -- you said  4 that -- you agreed that oxidizing agents -- that  5 certain oxidizing agents can oxidize polypropylene, and  6 I said especially when the inflammatory response is  7 chronic.</p> <p>8 A If the oxidizing environment is persistent,  9 then it has the potential to consistently -- or  10 persistently oxidize the polypropylene.</p> <p>11 Q Because it's a vicious cycle, right?</p> <p>12 MR. HUTCHINSON: Object to the form.</p> <p>13 Q (By Mr. Thornburgh) Of the macrophages  14 that's causing this invasion in the tissue, right?</p> <p>15 A Sure.</p> <p>16 MR. HUTCHINSON: Object -- hold on just  17 a minute, Dr. MacLean. Object to form.</p> <p>18 THE WITNESS: That hypothetical is true;  19 however, that is exactly why there are  20 antioxidants in the Prolene formulation to  21 combat the environment that you just  22 described, and we know it does it  23 successfully.</p> <p>24 Q (By Mr. Thornburgh) Do you know Dr. Wood?</p>
<p style="text-align: center;">Page 123</p> <p>1 Q And those chemicals include superoxides and  2 oxidized -- and peroxides?</p> <p>3 A Correct.</p> <p>4 Q And peroxide and superoxides are the body's  5 way of trying to -- during the frustrated phagocytosis,  6 to try to gobble up the foreign material to get rid of  7 it, expel it from the body, right?</p> <p>8 MR. HUTCHINSON: Object to form.</p> <p>9 THE WITNESS: Generally speaking, yes.</p> <p>10 Q (By Mr. Thornburgh) And peroxides and  11 superoxides are oxidizing agents, correct?</p> <p>12 A They can be.</p> <p>13 Q And oxidizing agents can oxidize  14 polypropylene?</p> <p>15 MR. HUTCHINSON: Object to form.</p> <p>16 THE WITNESS: It can oxidize  17 polypropylene. Oxidizing agents -- certain  18 oxidizing agents can oxidize polypropylene.</p> <p>19 Q (By Mr. Thornburgh) Especially when the  20 inflammatory response is chronic, right?</p> <p>21 MR. HUTCHINSON: Object to the form.</p> <p>22 Counsel, you've asked him several questions  23 about biocompatibility, and he's told you  24 he's not an expert in that area.</p>	<p style="text-align: center;">Page 125</p> <p>1 A I do not.</p> <p>2 Q Do you know Dr. Bachman or Dr. Grant?</p> <p>3 A I do not.</p> <p>4 Q Do you know Dr. Ramshaw?</p> <p>5 A I do not.</p> <p>6 Q You've never heard of Dr. Ramshaw, polymer  7 scientist, been studying the degradation of implantable  8 polypropylene meshes for the better part of 25 years?</p> <p>9 MR. HUTCHINSON: Object to form.</p> <p>10 THE WITNESS: Are you asking me if I  11 know him or have I heard of him?</p> <p>12 Q (By Mr. Thornburgh) Do you know?</p> <p>13 A I do not know him.</p> <p>14 Q Have you heard of him?</p> <p>15 A I've heard of him.</p> <p>16 Q Do you understand that he's been studying  17 degradation of polypropylene meshes, including Prolene  18 meshes, for the better part of 25 years?</p> <p>19 MR. HUTCHINSON: Object to form.</p> <p>20 THE WITNESS: I believe so.</p> <p>21 Q (By Mr. Thornburgh) You started studying  22 it -- let me ask you this question: When did Ethicon's  23 lawyers hire you in this case?</p> <p>24 A I think we were retained with a verbal</p>

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1      agreement sometime in May and retained in early June.	1      A I don't disagree with that.
2      Q Okay. So these polymer scientists and	2      Q You agree that -- you agree with that
3      biological -- and the department of biological	3      statement?
4      engineering at the University of Missouri, that's a --	4      A Just repeat that last piece. I want to make
5      that's a good school, right?	5      sure we're saying the same thing.
6      A I don't have any -- I don't have any opinion	6      Q Yeah, that the primary attack of -- on the
7      on that school one way or the other.	7      material is from neutrophils and macrophages, which
8      Q Do you know about its polymer science	8      stimulated -- which are stimulated upon injury or
9      program?	9      implantation. The cells release lysosomal enzymes and
10     A Not specifically.	10     oxidants that can actively break down some of the mesh
11     Q Do you know about its mesh investigations?	11     materials.
12     A Not specifically.	12     MR. HUTCHINSON: Object to form.
13     Q Do you know about the work that the school	13     THE WITNESS: Right, and I would say in
14     and these scientists have done with Ethicon?	14     the -- in the context of Prolene being the
15     A I may have read it somewhere, but not	15     implanted material, I don't agree with
16     specifically.	16     that.
17     Q Did Ethicon show you any internal documents	17     Q (By Mr. Thornburgh) You agree that for other
18     concerning Dr. Ramshaw and Ethicon's consulting work	18     polypropylene materials manufactured by other
19     with Dr. Ramshaw to investigate whether or not Prolene	19     manufacturers for the use as urogynecologic mesh
20     degrades?	20     devices, that those materials may break down as a
21     MR. HUTCHINSON: Object to form.	21     result of the oxidative attack through this immunologic
22     THE WITNESS: I don't remember.	22     response, but not Prolene, right?
23     Q (By Mr. Thornburgh) If Ethicon had internal	23     MR. HUTCHINSON: Object to form.
24     documents concerning studies that were being conducted	24     THE WITNESS: I haven't studied any
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1      by Dr. Ramshaw and his colleagues at the University of	1      other mesh material besides Prolene, with the
2      Missouri paid for by grant of Ethicon, you would expect	2      exception of the other candidate materials
3      Ethicon and Ethicon's lawyers to provide those to you,	3      that Ethicon had looked at in their studies
4      right?	4      in the '80s and '90s.
5      A They may have been part of the production. I	5      Q (By Mr. Thornburgh) Like PVDF?
6      just don't remember.	6      A Correct.
7      Q These scientists go on to say, "Synthetic	7      Q "The resulting degradation inflicted on the
8      meshes are recognized as foreign bodies and thus are	8      mesh and the resulting effect on the patient is a
9      subjected to various enzymatic attacks by the body.	9      subject which requires investigation in order to
10     The primary attack on the material is from neutrophils	10     understand the mesh material-patient interactions and
11     and macrophages, which are stimulated upon injury or	11     ultimately improve future mesh-material designs,"
12     implantation. The cells release lysosomal enzymes."	12     right?
13     Do you know what lysosomal enzymes are?	13     A That's what it says.
14     A Yes. They're protein.	14     Q This is dated 2013, right?
15     Q You're saying that lysosomal enzymes are a	15     A Yep.
16     type of protein?	16     Q And we're going to get to the Ethicon studies
17     A Enzymes are protein, so yes.	17     in a moment.
18     Q And then they -- and oxidants, do you see	18     A Great.
19     that?	19     Q But those internal Ethicon studies from the
20     A I do.	20     1980s and 1990s, to your knowledge, were never
21     Q That can actively break down some of the mesh	21     published to the general medical and scientific
22     material?	22     communities, correct?
23     A Yeah.	23     A No. They're internal documents, to my
24     Q Okay, you disagree with that?	24     knowledge. It might have been very helpful for them to

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<p>1 know that.</p> <p>2 Q And if you turn to page 1116. See the SEM</p> <p>3 section? 1116.</p> <p>4 A Yes, I do.</p> <p>5 Q "SEM micrographs can be seen in Figure 2.</p> <p>6 Micrographs of the pristine polypropylene mesh</p> <p>7 displayed relatively smooth surfaces with signs of</p> <p>8 extrusion while explanted polypropylene showed signs of</p> <p>9 crazing/surface cracking which is indicative</p> <p>10 oxidation."</p> <p>11 You would agree with me that crazing and</p> <p>12 cracking is indicative of polypropylene oxidation,</p> <p>13 right?</p> <p>14 MR. HUTCHINSON: Object to form.</p> <p>15 THE WITNESS: It can be if you're -- if</p> <p>16 you've assured yourself that the material</p> <p>17 you're looking is polypropylene, oxidized</p> <p>18 polypropylene.</p> <p>19 Q (By Mr. Thornburgh) It has cracks that run</p> <p>20 perpendicular to the extrusion lines, right?</p> <p>21 MR. HUTCHINSON: Object to form.</p> <p>22 THE WITNESS: Oxidized polypropylene, if</p> <p>23 oxidized enough and degraded enough, can</p> <p>24 ultimately manifest in cracking.</p>	<p>1 A Uh-huh.</p> <p>2 Q Looking at explanted material, testing it</p> <p>3 with -- against the control, which is the pristine,</p> <p>4 unused mesh right out of the box, right?</p> <p>5 A That is correct.</p> <p>6 Q "And the scan revealed a large peak at 1740</p> <p>7 centimeters, indicative of carbonyl groups (CO), that</p> <p>8 was not evident in the pristine sample. This</p> <p>9 correlates with free radical formation and oxidation of</p> <p>10 the polypropylene mesh while in vivo." Did I read that</p> <p>11 correctly?</p> <p>12 A You read that correctly.</p> <p>13 Q And if we turn the page, we have Exhibit --</p> <p>14 we have Figure 2, which shows the pristine Prolene mesh</p> <p>15 as -- in Figure A and D as the explanted mesh that was</p> <p>16 analyzed using scanning electron microscopy, right?</p> <p>17 A Correct.</p> <p>18 MR. THORNBURGH: We have to change the</p> <p>19 tape.</p> <p>20 THE VIDEOGRAPHER: We are now going off</p> <p>21 the video record. The time is currently</p> <p>22 12:28 p.m. This is the end of Tape No. 2.</p> <p>23 (Lunch recess taken.)</p> <p>24 THE VIDEOGRAPHER: We are now back on</p>
<p style="text-align: center;">Page 131</p> <p>1 Q If you go to the --</p> <p>2 MR. THORNBURGH: How much time do we</p> <p>3 have left?</p> <p>4 THE VIDEOGRAPHER: Two minutes.</p> <p>5 Q (By Mr. Thornburgh) If you go to the</p> <p>6 "ATR-FTIR," have you run any ATR or FTIR experiments on</p> <p>7 polypropylene Prolene mesh material?</p> <p>8 A Yes, I've run IR on exemplar Prolene</p> <p>9 material.</p> <p>10 Q Is that contained within your --</p> <p>11 A It is.</p> <p>12 Q -- Exhibit 5?</p> <p>13 A It is.</p> <p>14 Q Okay. Have you run any IR on explanted</p> <p>15 polypropylene material?</p> <p>16 A I have not. Many others have, and that data</p> <p>17 I have reviewed.</p> <p>18 Q It goes on to say, "The scans revealed" --</p> <p>19 and I'm talking about FTIR -- "The scans revealed a</p> <p>20 large peak" -- we're talking about polypropylene,</p> <p>21 right? "Figure 3 shows representative spectrum</p> <p>22 collected from the explanted polypropylene mesh along</p> <p>23 with a spectrum of pristine polypropylene mesh."</p> <p>24 Looking at the control, right?</p>	<p style="text-align: center;">Page 133</p> <p>1 the video record with Tape No. 3. The time</p> <p>2 is currently 1:37 p.m.</p> <p>3 Q (By Mr. Thornburgh) Hi, Doctor. Before we</p> <p>4 took our lunch break, we were talking about the Wood</p> <p>5 article. Doctor, what are free radicals?</p> <p>6 A Free radicals are when -- for example, when</p> <p>7 you take a peroxide that's in the neighborhood of a</p> <p>8 polypropylene or a polyethylene type polymer, it</p> <p>9 actually can create a free radical or basically a free</p> <p>10 proton or electron on the polymer that gives it the</p> <p>11 ability to react with other molecules.</p> <p>12 Q And a free radical can degrade the</p> <p>13 polypropylene, correct?</p> <p>14 A A free radical can attack the polypropylene</p> <p>15 chain, correct.</p> <p>16 Q Attack it and degrade it, right?</p> <p>17 A Correct.</p> <p>18 Q And that can be without oxygen species,</p> <p>19 right?</p> <p>20 A You can create -- yes, you can do -- you can</p> <p>21 have thermal oxidation, for example, where you just</p> <p>22 have too much heat put into the polymer. That can</p> <p>23 break a polymer bond, covalent polymer bond, latch on</p> <p>24 to available oxygen that's just in the air, for</p>

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<p>1 example, and can cause oxidation. That's possible.  2 Q And that's what was -- that's the mechanism  3 of degradation that's described in the Wood article,  4 correct?  5 A Yes, that free radicals are formed in the  6 presence of peroxides.  7 Q And when we went off the record, we were  8 looking at the scanning electron microscopy images on  9 page 1117 of Exhibit 8. And you see that the Figure 2A  10 is the pristine polypropylene mesh that was analyzed,  11 and D is the explanted polypropylene mesh that was  12 analyzed, correct?  13 A Correct, that's what it says.  14 Q And you can see in Exhibit D surface changes  15 or cracking in the surface of the polypropylene fibers,  16 correct?  17 A No, I would not say that that's conclusive  18 that that is cracking in the polypropylene.  19 Q Well, we've got cracking in the image and we  20 also have the FTIR carbonyl group to the right of  21 the -- or just below the images, which shows a carbonyl  22 peak at 1740, correct?  23 A Correct. But as we talked about earlier, the  24 cleaning was not successful.</p>	<p>1 foreign body response. Because of this, polypropylene  2 has been shown to oxidize in vivo."  3 Do you agree or disagree with those  4 statements?  5 A What page are you on?  6 Q Page 1120 of Exhibit 8 under "Polypropylene."  7 A I agree that polypropylene can degrade in an  8 oxidizing environment. I agree with that statement.  9 Q And do you agree that oxidation of  10 polypropylene results in surface crazing and cracking,  11 changes in the mechanical strength, and increased  12 brittleness?  13 A I agree with those things. Yes, that's  14 all -- that's all correct.  15 Q And it goes on to say, "The SEM image shown  16 in Figure 2D demonstrates obvious crazing and cracking  17 of the explanted polypropylene specimen as compared to  18 the pristine." Do you disagree with that?  19 A I disagree with -- if you interpret that  20 as -- if you interpret that as the crazing and cracking  21 is definitively taking place in polypropylene and no  22 other material, then I disagree with that.  23 Q The authors go on to say that the --  24 "Additionally, ATR-FTIR spectra in Figure 3 confirmed</p>
<p style="text-align: center;">Page 135</p> <p>1 Q It's your opinion that the cleaning was not  2 successful?  3 A It's not my opinion. It's actually -- it's  4 in the -- it's in the report.  5 Q Do you have an opinion whether or not the  6 polypropylene -- strike that.  7 Do you have an opinion that the conclusions  8 in the Wood article are incorrect and that the  9 polypropylene did not actually oxidize?  10 A I think the data says it's inconclusive that  11 it was an oxidation mechanism that caused that  12 cracking.  13 Q And so you disagree with the conclusions of  14 the Wood scientist, correct?  15 MR. HUTCHINSON: Object to form.  16 Q (By Mr. Thornburgh) You disagree with the  17 authors of the Wood article, correct?  18 MR. HUTCHINSON: Same objection.  19 Q (By Mr. Thornburgh) If you turn to --  20 A I disagree with their definitive conclusion  21 that it was oxidation.  22 Q And if you turn to page 1120 of Exhibit 8, it  23 says, "Unfortunately, polypropylene will degrade in an  24 oxidizing environment, such as the environment during a</p>	<p style="text-align: center;">Page 137</p> <p>1 the presence of carbonyl peaks which are indicative of  2 surface oxidation."  3 Do you agree or disagree with that statement?  4 A Neither. I'd say that that's only part of  5 the potential reasoning that those carbonyl peaks would  6 be present. As I mentioned earlier, there are other  7 species that are available in vivo that are going to  8 have carbonyl functionality to them. And this -- these  9 authors have not ruled out those additional molecules  10 that we know are present.  11 Q Did you also note that these authors also  12 performed additional studies, the -- you see the MDSC  13 data displayed in Figure 6?  14 A Yes, I do.  15 Q And did you also note that the authors found  16 that the explanted samples displayed a lower heat  17 effusion and lower melt temperatures?  18 A Correct, but I explained earlier that that  19 lower -- that lower melt temperature can also be  20 assigned to having the material being plasticized.  21 Q By -- when you say "plasticized," are you  22 talking about the formaldehyde-protein bond?  23 A I am not.  24 Q What are you talking about?</p>

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<p>1        A I'm talking about the ester-based molecules  2        that Dr. Jordi found and was able to extract out of  3        filament in the Bellew matter that clearly tell us that  4        the material is being -- that the material is being  5        plasticized. So that is the diffusion of small  6        aliphatic ester molecules into the material that's  7        causing it to increase its toughness, increase its  8        flexibility, and suppress its melt temperature.</p> <p>9        Q So you disagree with the Wood authors that  10       these findings were indicative of chemical changes  11       within the bulk structure of the material?</p> <p>12       A Where are you? Where did you cite that from?</p> <p>13       Q It's the next sentence after the heat of  14       effusion and low melt temperature sentence that we just  15       read on page 1120.</p> <p>16       A I don't disagree that that's what they got  17       for data. I disagree that you can affirmatively  18       ascribe that behavior to oxidation and solely  19       oxidation.</p> <p>20       Q If you turn to 1121 under the conclusions.</p> <p>21       A Uh-huh.</p> <p>22       Q Are you there?</p> <p>23       A I am.</p> <p>24       Q It says, the second sentences, "The</p>	<p>1        "Used FTIR?"  2        "Yes, sir."  3        "FTIR to determine whether or not that mesh  4        had degraded?"  5        "I do. The Wood article, now, we're talking  6        about."  7        "All right." Question: "All right. And  8        you've testified that in that study, the mesh did  9        degrade as a result of oxidation, and the band at 1740  10       confirmed that it had degraded as a result of  11       oxidation, correct?"  12       Dr. Thamess' answer: "I did."  13       Page 85, line 7, "Dr. Wood found a carbonyl  14       peak on FTIR of oxidized degraded polypropylene mesh at  15       1740, right?"  16       "That's correct, sir."  17       Question: "And you agree that the  18       polypropylene mesh had degraded as a result of  19       oxidation, correct?"  20       Answer: "That's correct, sir."  21       "Do you disagree with Dr. Thamess" --  22       MR. HUTCHINSON: I'm going to object --  23       Q -- "your colleague, an expert in this case?"  24       MR. HUTCHINSON: I'm going to object to</p>
<p style="text-align: center;">Page 139</p> <p>1        polypropylene mesh demonstrated chemical degradation  2        via oxidation, permanent distortion of the mesh, and  3        changes in thermal properties." It goes on to say,  4        "While the results of the characterization study showed  5        that polypropylene will undergo oxidation."  6        Do you disagree with those conclusions from  7        these authors?</p> <p>8        A I disagree that those are the only way to get  9        the changes that they observed, by -- oxidation is the  10       only way to get to those changes.</p> <p>11       Q Dr. Thamess testified in the Bellew case  12       starting on page 83, line 7 -- strike that.</p> <p>13       If you turn to page 84 --</p> <p>14       MR. HUTCHINSON: Counsel, do you have a  15       copy for us?</p> <p>16       MR. THORNBURGH: No. I'm happy to show  17       you.</p> <p>18       Q (By Mr. Thornburgh) Eighty-four, line 1,  19       question: "Well, Doctor, you've testified previously  20       regarding -- remember looking at the Wood article?"  21       "Yes, sir." Answer: "Yes, sir, I do."  22       Question: "Which is another polypropylene  23       mesh?"  24       "Yes, sir."</p>	<p style="text-align: center;">Page 141</p> <p>1        form to the extent you've asked the witness  2        to interpret a segment of a deposition  3        transcript and especially without showing him  4        the copy of the deposition.</p> <p>5        MR. THORNBURGH: No speaking -- you get  6        to object.</p> <p>7        MR. HUTCHINSON: Then that's my  8        objection.</p> <p>9        Q (By Mr. Thornburgh) I'll show it to you.  10       "And Dr. Wood found a carbonyl peak on FTIR of oxidized  11       degraded polypropylene mesh at 1740, right?"  12       "That's correct, sir."  13       Question: "And you agree that the  14       polypropylene mesh had degraded as a result of  15       oxidation, correct?"  16       "That's correct, sir."  17       Question: "As confirmed by the peak at  18       1740?"  19       Answer: "Correct."  20       You disagree with Dr. Thamess's opinion  21       regarding the Wood article and the conclusions of the  22       Wood scientists and researchers?  23       A I --  24       MR. HUTCHINSON: Same objection.</p>

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<p>1        THE WITNESS: I disagree that that is  2        the sole explanation for the changes that had  3        taken place in the Wood article.</p> <p>4        MR. THORNBURGH: We're done with  5        Exhibit 8.</p> <p>6        Q (By Mr. Thornburgh) You reviewed some  7        other -- some internal documents from Ethicon, correct,  8        some internal Ethicon documents?</p> <p>9        A I -- yes, hundreds.</p> <p>10      Q And the Ethicon internal documents that you  11     reviewed were selected and provided to you by Ethicon's  12     lawyers, correct?</p> <p>13      A Again, they sent me waves of documents, and  14     along the way I may have asked for more information, so  15     I wouldn't say it was a one-way street.</p> <p>16      Q Well, what things did you ask for?</p> <p>17      A I don't recall.</p> <p>18      Q What types of things did you ask for?</p> <p>19      A I don't recall. I just remember reviewing  20     documents. We'd have some conversations. I may have  21     asked for more information and they may have provided  22     it.</p> <p>23      Q Well, what things were produced to you by  24     Ethicon's attorneys?</p>	<p>1        remember reading six volumes of his testimony.</p> <p>2        Q So you only read whatever volumes were  3        provided to you by Ethicon, correct?</p> <p>4        A Or they could have provided all the volumes  5        to me and I may have skimmed some and read some.</p> <p>6        Q And they provided you with some of the  7        literature?</p> <p>8        A Some literature. A lot of the literature we  9        found on our own, but some of the literature came from  10      them.</p> <p>11      Q They provided you with Wood article, the  12      Clave article, the Costello article, the Mary article,  13      right?</p> <p>14      MR. HUTCHINSON: Objection. Compound.</p> <p>15      THE WITNESS: I just -- they could have.  16      I just don't recall. Again, just look at the  17      list and it will tell you what they sent  18      me.</p> <p>19      Q (By Mr. Thornburgh) The materials that  20     Ethicon's lawyers chose to provide you and which you  21     are relying on are listed in your report at the index,  22     right?</p> <p>23      A Correct.</p> <p>24      Q Appendix C?</p>
<p style="text-align: center;">Page 143</p> <p>1        A Whatever is listed in my files reviewed.</p> <p>2        Q So the case-specific materials, the internal  3        Ethicon documents, right?</p> <p>4        A Correct. You can go to that second appendix  5        in my document; it will list exactly what they sent me.</p> <p>6        Q The expert reports, correct?</p> <p>7        A Correct.</p> <p>8        Q The depositions?</p> <p>9        A Correct.</p> <p>10      Q Which depositions did you read in this case?</p> <p>11      A Guelcher's, one or two Iakovlev depositions,  12      Jordi deposition, Thames' Bellew deposition. Those are  13      the ones I remember off the top of my head.</p> <p>14      Q Did you read any depositions of the -- of any  15      of Ethicon's internal employees or former employees?</p> <p>16      A Yes. I recall --</p> <p>17      Q Which --</p> <p>18      A -- reading Thomas Barbolt's deposition.</p> <p>19      Q Which -- one volume, two volumes, three  20      volumes? How many volumes did you read?</p> <p>21      A I don't recall.</p> <p>22      Q You didn't read six volumes of deposition  23      testimony from Dr. Barbolt, did you?</p> <p>24      A I don't -- no, I don't remember -- I don't</p>	<p style="text-align: center;">Page 145</p> <p>1        A Correct.</p> <p>2        MR. HUTCHINSON: Object to form.</p> <p>3        Q (By Mr. Thornburgh) And what was the purpose  4        of -- what did Ethicon ask you to do in this case, or  5        Ethicon's lawyers?</p> <p>6        A I think we've talked about it a couple of  7        times. They asked me to take a look at the universe of  8        documents that they provided, many of which of them are  9        Ethicon documents, internal documents, internal  10      studies, external studies, public literature, all the  11      things that we've talked about, synthesize and review  12      that information and determine, to the best of my  13      ability, if the Prolene material is being degraded by  14      some sort of oxidative degradation mechanism.</p> <p>15      Q Did they -- they also asked you to run some  16      studies at your lab?</p> <p>17      A They didn't ask. I actually had proposed  18      that work to them.</p> <p>19      Q Okay. And if we -- in Exhibit No. 2, do you  20      have the work that you performed at your -- at your lab  21      or which was performed on your behalf?</p> <p>22      A Are you asking me if I have the --</p> <p>23      Q The microscopic work that you did.</p> <p>24      A Yes, I have -- I have that report in front of</p>

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<p>1       me.</p> <p>2       Q    Okay. And what did -- what did Exponent do</p> <p>3       to test -- what types of studies did Ethicon do on the</p> <p>4       polypropylene/Prolene TVT mesh exemplars that were</p> <p>5       received from Ethicon?</p> <p>6       A    You said "Ethicon" in the beginning of that</p> <p>7       sentence.</p> <p>8       Q    Sorry. What did Exponent do? What studies</p> <p>9       did Ethicon conduct?</p> <p>10      A    Okay. Well, we set up an experiment to</p> <p>11       really test three hypotheses. The first hypothesis was</p> <p>12       does oxidized or unoxidized polypropylene stain with</p> <p>13       H&amp;E staining. The second hypothesis was does H&amp;E stain</p> <p>14       have the ability to mechanically trap, as posited by</p> <p>15       Dr. Iakovlev. And the third is can you manipulate</p> <p>16       polarized light to get artifacts that might suggest</p> <p>17       some sort of bark layer that really isn't there.</p> <p>18      Q    Okay. So you were asked to check the -- to</p> <p>19       test the hypothesis does oxidized or unoxidized</p> <p>20       polypropylene stain with H&amp;E staining?</p> <p>21      A    Correct.</p> <p>22      Q    The hypothesis -- also, the second hypothesis</p> <p>23       was does H&amp;E stain have the ability to mechanically</p> <p>24       trap as deposited?</p>	<p>1       MR. THORNBURGH: Well, can I get the</p> <p>2       court reporter to read it back.</p> <p>3       MR. HUTCHINSON: I just want to know</p> <p>4       what the first hypothesis was.</p> <p>5       MR. THORNBURGH: The first -- sorry, can</p> <p>6       I go ahead and read it?</p> <p>7       (Discussion off the written record.)</p> <p>8       MR. HUTCHINSON: I just want to know if</p> <p>9       you said polypropylene or Prolene. That's</p> <p>10       all I'm wanting to know. I just didn't hear</p> <p>11       you.</p> <p>12      MR. THORNBURGH: I asked the witness</p> <p>13       what Exponent was asked to do or what they</p> <p>14       did. The response was, "We set up an</p> <p>15       experiment to really test three hypotheses.</p> <p>16       The first hypothesis was does oxidized or</p> <p>17       unoxidized polypropylene stain with H&amp;E</p> <p>18       staining. The second hypothesis was does H&amp;E</p> <p>19       stain have the ability to mechanically trap,</p> <p>20       as posited by Dr. Iakovlev. And the third is</p> <p>21       can you manipulate polarized light to get</p> <p>22       artifacts that might suggest some sort of</p> <p>23       layer" --</p> <p>24      MR. HUTCHINSON: Okay.</p>
<p style="text-align: center;">Page 147</p> <p>1       A    As posited.</p> <p>2       Q    As posited by Dr. Iakovlev. And the third</p> <p>3       was can you manipulate polarized light to get artifacts</p> <p>4       that might suggest some sort of layer. Is that what</p> <p>5       your -- the scope of your testing was?</p> <p>6       MR. HUTCHINSON: And, Counsel, just so</p> <p>7       we're clear, on the first hypothesis that you</p> <p>8       were asking about, were you asking about</p> <p>9       unoxidized polypropylene or Prolene? I</p> <p>10       didn't hear you correctly.</p> <p>11      MR. THORNBURGH: Hold on. I asked him</p> <p>12       what studies he did --</p> <p>13      MR. HUTCHINSON: Okay.</p> <p>14      MR. THORNBURGH: -- and he told me --</p> <p>15      MR. HUTCHINSON: Okay. I'm just -- I'm</p> <p>16       just --</p> <p>17      MR. THORNBURGH: -- that those were the</p> <p>18       three studies he did.</p> <p>19      MR. HUTCHINSON: I didn't -- I didn't</p> <p>20       understand what you said.</p> <p>21      MR. THORNBURGH: He was testing three</p> <p>22       hypotheses.</p> <p>23      MR. HUTCHINSON: Okay, my bad. And what</p> <p>24       was the first one, my question?</p>	<p style="text-align: center;">Page 149</p> <p>1       MR. THORNBURGH: -- "that really isn't</p> <p>2       there."</p> <p>3       MR. HUTCHINSON: That's all I want to</p> <p>4       know.</p> <p>5       THE WITNESS: Okay. Yeah.</p> <p>6       Q    (By Mr. Thornburgh) Okay. And --</p> <p>7       A    And I just -- I just need to clarify for the</p> <p>8       record. I should have said Prolene. It's in the</p> <p>9       report. When I said polypropylene earlier, the</p> <p>10       hypothesis testing unoxidized and oxidized Prolene.</p> <p>11      Q    Now, I'm correct that Ethicon adds</p> <p>12       antioxidants to their resin, correct?</p> <p>13      A    Correct.</p> <p>14      Q    And you had talked about primary and</p> <p>15       secondary antioxidants?</p> <p>16      A    Correct.</p> <p>17      Q    And we're going to talk about some documents,</p> <p>18       but we're also going to talk about your expert report</p> <p>19       that we've -- and your testing. But are there three</p> <p>20       types of -- how many different types of additives are</p> <p>21       used in polypropylene devices to prevent oxidation?</p> <p>22      A    I'm not sure I understand your question.</p> <p>23      Q    What are the different types of -- you talked</p> <p>24       about primary and secondary antioxidants. Are those</p>

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<p>1 the only antioxidants that are used to retard oxidation 2 and degradation?</p> <p>3 A Those are two specific types. One is DLTDP 4 and one is a thioester. So the first one is a hindered 5 phenol antioxidant used in a lot of olefin materials, 6 including polypropylene. It's a hindered phenol. That 7 is a primary and that is a radical scavenger, 8 free-radical scavenger; and then the thioester, which 9 is the DLTDP.</p> <p>10 Q Is what?</p> <p>11 A Secondary.</p> <p>12 Q And what is the -- what is -- what's the 13 difference between primary and secondary?</p> <p>14 A Well, primary antioxidant is actually -- we 15 talked about the free -- the free radicals that 16 actually take place in the chemistry. They are 17 free-radical scavengers, so they go out and actually 18 bond or bind onto those free radicals that are 19 generated to stop that autocatalytic reaction that we 20 talked about earlier.</p> <p>21 The thioester is the secondary additive, and 22 that goes out and actually neutralizes, chemically 23 neutralizes those peroxides that can cause the free 24 radicals to form. So it's kind of a double-fisted</p>	<p>1 how it's referred to and documented in the scientific 2 literature. And again, they're synergistic, they're 3 working in harmony, they're working together to combat 4 those two mechanisms that we talked about.</p> <p>5 Q And what is Ethicon's thioester?</p> <p>6 A It's the DLTDP.</p> <p>7 Q And the basis for that opinion or 8 understanding?</p> <p>9 A It's -- I got it from there -- Ethicon's 10 literature, Ethicon's internal documents. That's the 11 antioxidant -- that's the secondary antioxidant that 12 they use in the formulation of Prolene.</p> <p>13 Q And the reason why Ethicon -- the reason 14 why -- well, is it your understanding that the reason 15 why Ethicon uses Santanox and DLTDP is because 16 polypropylene will degrade without a retarding 17 additive?</p> <p>18 A In certain oxidizing environments, it has 19 that potential, and that's why you put the antioxidants 20 in it, to negate that potential.</p> <p>21 (Exhibit 9 marked for identification.)</p> <p>22 Q (By Mr. Thornburgh) I'm handing you 23 what I've marked as Exhibit No. 9, which is the 24 February 21st, 2003 Ethicon internal document and a --</p>
<p style="text-align: center;">Page 151</p> <p>1 approach, if you will.</p> <p>2 Q What are thioesters?</p> <p>3 A I just answered that.</p> <p>4 Q I didn't understand your description of it.</p> <p>5 A They are small molecules that go out and find 6 peroxides and neutralize them so they can't cause 7 subsequent damage to the polypropylene.</p> <p>8 Q Okay. And what is -- what's your 9 understanding of Ethicon's primary antioxidant?</p> <p>10 A Santanox R, which is the hindered phenol that 11 we talked about a few minutes ago.</p> <p>12 Q And what's the basis for your understanding 13 that the Santanox R is the primary antioxidant used by 14 Ethicon?</p> <p>15 A Because that's how it's discussed in the 16 polymer literature, that it's the primary antioxidants 17 that goes off and basically latches on to those 18 free-radical sites that we talked about and stops that 19 autocatalytic oxidation process.</p> <p>20 Q And the secondary is DLTDP?</p> <p>21 A Correct.</p> <p>22 Q That's your understanding. And what's the 23 basis for that understanding?</p> <p>24 A Same discussion, it's just -- well, that's</p>	<p style="text-align: center;">Page 153</p> <p>1 attached to the email is a report by Dr. John Karl. 2 Have you seen this document before?</p> <p>3 A I believe I have.</p> <p>4 Q You see on the -- on the email from February 5 2003, February 21st, 2003, the first page of Exhibit 9, 6 there's a discussion about what the -- what are the 7 additives within the Prolene resin. And if you look to 8 the last paragraph, it says, "If there is any 9 biocompatibility and/or safety documents for Prolene, 10 it should have addressed the additives and made some 11 worst-case estimates."</p> <p>12 Did you look at any internal documents or 13 internal studies testing the internal additives of the 14 Prolene resin to determine biocompatibility?</p> <p>15 A Sure. I've seen several documents that 16 support the biocompatibility of the material.</p> <p>17 Q My question was: Did you specifically review 18 any documents that looked at the biocompatibility of 19 the additives that are contained within the Prolene 20 resin?</p> <p>21 A Well, that would be part of the testing 22 program. When I'm -- when I'm testing Prolene for 23 biocompatibility, I'm testing the entire formulation, 24 which would include the additives that we just talked</p>

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<p>1 about.</p> <p>2 Q My question was: Did you review any internal</p> <p>3 Ethicon documents that looked at -- specifically looked</p> <p>4 at the biocompatibility of the Prolene additives,</p> <p>5 including Santanox R and Procol?</p> <p>6 MR. HUTCHINSON: Object to form. Been</p> <p>7 asked and answered, Counsel.</p> <p>8 THE WITNESS: Yeah, it's the same</p> <p>9 answer.</p> <p>10 Q (By Mr. Thornburgh) You're not answering my</p> <p>11 question. My question was: Did you look at --</p> <p>12 specifically look at any testing of the Santanox R or</p> <p>13 the Procol LA?</p> <p>14 A Oh, I don't recall if there's any testing</p> <p>15 that was isolated to the additives themselves, but the</p> <p>16 testing that was done would have included those</p> <p>17 additives in it because they are part of the Prolene</p> <p>18 formulation.</p> <p>19 Q Aren't there requirements under the 10993 --</p> <p>20 ISO 10993 requirements and guidelines to test the</p> <p>21 additives that are within a permanent implantable mesh</p> <p>22 material?</p> <p>23 A There are, but the specific pieces of 10993</p> <p>24 that you test to is often negotiated with FDA. So it's</p>	<p>1 the protein fibers?</p> <p>2 MR. HUTCHINSON: Object to form.</p> <p>3 THE WITNESS: I have not seen any data</p> <p>4 that suggests that that's happening.</p> <p>5 Q (By Mr. Thornburgh) Did you read any</p> <p>6 depositions that -- by Ethicon's witnesses who tested</p> <p>7 for leaching who concluded that the additives in the</p> <p>8 Prolene device and the TVT device do leach out of the</p> <p>9 Prolene fibers?</p> <p>10 MR. HUTCHINSON: Object to form.</p> <p>11 THE WITNESS: I don't recall seeing that</p> <p>12 data. I need to see a -- I need to see a</p> <p>13 document.</p> <p>14 Q (By Mr. Thornburgh) Did Ethicon show you</p> <p>15 that deposition?</p> <p>16 A I don't recall. I remember -- I remember Tom</p> <p>17 Barbolt making some of those comments in his</p> <p>18 deposition. I don't recall seeing any test data or</p> <p>19 supportive information.</p> <p>20 Q You understand that Dr. Barbolt was the</p> <p>21 person responsible for --</p> <p>22 A I do.</p> <p>23 Q -- for overseeing those studies?</p> <p>24 A I do.</p>
<p style="text-align: center;">Page 155</p> <p>1 very material and application specific.</p> <p>2 Q That wasn't my question. My question was:</p> <p>3 There are requirements to test the additives of</p> <p>4 permanent implantable devices, correct?</p> <p>5 MR. HUTCHINSON: Object to form.</p> <p>6 THE WITNESS: There is a test within the</p> <p>7 standard that -- there's a test within the</p> <p>8 standard that does call out testing of</p> <p>9 additives, correct.</p> <p>10 Q (By Mr. Thornburgh) And the purpose for that</p> <p>11 is because additives can leach out of the implantable</p> <p>12 or implanted medical device, correct?</p> <p>13 MR. HUTCHINSON: Object to form.</p> <p>14 THE WITNESS: I think that is -- yes,</p> <p>15 that's one of the reasons why that test is</p> <p>16 done or can be done, correct.</p> <p>17 Q (By Mr. Thornburgh) And those additives</p> <p>18 would include the Santanox R, the DLTDP, and the Procol</p> <p>19 LA-10, right?</p> <p>20 A Those are some of the additives in the</p> <p>21 formulation, correct.</p> <p>22 Q And do you agree that the additives,</p> <p>23 including the Santanox R, the Procol LA, the DLTDP, the</p> <p>24 calcium stearate, and the CPC pigment, can leach out of</p>	<p style="text-align: center;">Page 157</p> <p>1 Q So you would rely on Dr. Barbolt concerning</p> <p>2 whether or not Santanox or Procol or DLTDP can leach</p> <p>3 out of the fibers, right?</p> <p>4 MR. HUTCHINSON: Object to form.</p> <p>5 THE WITNESS: I would not rely on him.</p> <p>6 I'd want to see the data myself.</p> <p>7 Q (By Mr. Thornburgh) You haven't seen the</p> <p>8 data?</p> <p>9 A I don't recall seeing the data. If you have</p> <p>10 a document that suggests that or has test data that</p> <p>11 talks about leaching, I'd be happy to review it, but I</p> <p>12 just don't recall seeing it.</p> <p>13 Q So you don't have an opinion one way or the</p> <p>14 other?</p> <p>15 A As we sit here today, no, but I have not seen</p> <p>16 any data that suggests that.</p> <p>17 Q Did you ask the -- Ethicon's lawyers or</p> <p>18 Ethicon to provide you with any documents that</p> <p>19 would demonstrate whether or not DLTDP, Santanox R,</p> <p>20 Procol LA, or the other additives would leach out of</p> <p>21 the -- of the Prolene fibers?</p> <p>22 A I don't recall asking them that.</p> <p>23 Q If the additives leach out of the Prolene</p> <p>24 fibers in the TVT, including the antioxidants, that</p>

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<p>1 could leave the mesh fibers, the Prolene fibers, 2 susceptible to degradation, correct? 3 A Not necessarily. 4 Q Not necessarily? 5 A Correct. 6 Q Well, if there's a certain amount that's put 7 in to protect against degradation and over time, inside 8 the body, those additives leach out of the Prolene 9 fibers, that would increase the risk or the 10 susceptibility to oxidative degradation, correct? 11 A It depends on the rate it's happening. It 12 depends on the time scales we're talking about. Let's 13 just say, for example, hypothetically that leaching is 14 occurring and there is some migration of these 15 molecules out of the fiber. That still doesn't mean 16 that there's plenty still within the fiber to do its 17 job. These things are not put in -- these things are 18 put in in surplus so that they give a long-term effect. 19 So you would have to convince me that -- A, 20 that they're leaching out, and B, that they've leached 21 out enough to actually leave the material unprotected. 22 And there's no such data that I've seen. 23 Q Are you offering any opinions in this case 24 regarding the cytotoxicity of the TTV material?</p>	<p>1 A I have not. 2 Q And you haven't looked at the clinical 3 studies of the Prolene polypropylene mesh devices, 4 correct? 5 A I just don't remember. I don't remember if 6 I've -- it was not a focus of my work. So if I saw 7 them, I just don't remember them. 8 Q In order for you to form an opinion about 9 cytotoxicity and whether or not it's cytotoxic, the 10 polypropylene or the additives within the 11 polypropylene, you'd have to do a full review of the 12 literature to determine the rate of complications 13 associated with the product, right? 14 MR. HUTCHINSON: Object to form. 15 Counsel, he's not offering cytotoxicity 16 opinions. 17 MR. THORNBURGH: It's in his report, 18 so... 19 THE WITNESS: Where is it in my report? 20 MR. THORNBURGH: Go to Exhibit 2. If 21 you're not offering it, you're not offering 22 it. I'm fine with it. I just want to make 23 sure I understand what you're doing. 24 Q (By Mr. Thornburgh) "Prolene</p>
<p style="text-align: center;">Page 159</p> <p>1 A No, I'm not. 2 Q You're not going to come in and testify that 3 the TTV is not cytotoxic? 4 A I'm not going to offer that opinion. I have 5 not offered that opinion in my report. 6 Q You haven't reviewed any of the cytotoxicity 7 testing, correct? 8 A Well, no, I've reviewed a lot of those 9 documents. Yeah, I mean, there's rabbit studies, 10 there's -- there is rat studies. I believe there's a 11 dog study. So I've seen a lot of those documents. 12 I've reviewed them, synthesized them, but I'm not 13 offering any opinions on them. 14 Q Did you see the ISO lesion testing done of 15 the TTV Olmstead device which showed that it was 16 severely cytotoxic? 17 MR. HUTCHINSON: Object to form. 18 Q (By Mr. Thornburgh) The mesh? 19 A I did, but I also saw a couple of follow-up 20 reports that refute that data. I think there was a lot 21 of issues with how -- how much integrity was behind 22 that data and how it stacked up with other labs. 23 Q You haven't conducted any cytotoxicity 24 testing of the TTV device, correct?</p>	<p style="text-align: center;">Page 161</p> <p>1 Biocompatibility," do you see that section? 2 A What page are you on? 3 Q On page 20. It's the very last paragraph, 4 "In order for Prolene mesh to be used as a permanent 5 tissue implant, Ethicon must comply with ISO 10993 and 6 analyze the cytotoxicity, sensitization, and 7 genotoxicity, among other tests" -- 8 A Yes. 9 Q -- "of the Prolene mesh. The safety of the 10 Prolene mesh has been demonstrated through a long 11 history of clinical use of Prolene sutures." 12 You haven't looked at the long history of 13 clinical use of Prolene suture -- of the Prolene TTV 14 device? 15 A If the clinical studies that you're referring 16 to are the rabbit, the dog, the rat studies, et cetera, 17 then I have looked at those documents. 18 Q You understand that those are pre-clinical, 19 right? Do you understand the difference between 20 pre-clinical and clinical? 21 A I do. 22 Q Pre-clinical are studies that are done on 23 animals? 24 A Correct.</p>

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1       Q   Generally short-term studies?	1       whether or not the TVT device degrades in vivo?
2       A   Right.	2       MR. HUTCHINSON: Object to form.
3       Q   Don't demonstrate safety or -- safety or	3       THE WITNESS: I'm not sure I understand
4       effectiveness in humans?	4       your question.
5       MR. HUTCHINSON: Object to form.	5       Q (By Mr. Thornburgh) Are you going to limit
6       Q (By Mr. Thornburgh) Right?	6       your opinions at the trial in this case to degradation
7       A   Correct. But you have to realize I am	7       of polypropylene Prolene material?
8       actually just citing an internal Ethicon document	8       A I'm going to limit my opinions to anything
9       that --	9       that I tell you that's an opinion here today, in
10      Q   Well, I --	10      addition to whatever is listed as opinions in my
11      A   -- refers to those clinical studies.	11      report.
12      Q   I just want to know if you're going to offer	12      Q   But not cytotoxicity?
13      opinions about cytotoxicity at the trial in this case.	13      A   Correct.
14      A   I'm not.	14      Q   And not clinical studies?
15      Q   And you're not going to -- and you're not	15      A   Correct.
16      going to rely on that data for any opinions in this	16      Q   You talk about a 28-day rat study. That's a
17      case, right?	17      short-term study, right?
18      A   No, I'm not. I'm just stating that the	18      A   It is.
19      material has been demonstrated to be biocompatible	19      Q   And that 28-day rat study should not be
20      since 1969. It's been tested over and over and over	20      extrapolated to determine the long-term safety of the
21      again, and it's the same conclusion that it's	21      TVT mesh device, correct?
22      biocompatible. That's all I'm saying.	22      A I think it's one data point amongst many that
23      Q   Do you understand the general principles	23      you'd want to collect.
24      in -- with regard to biocompatibility or foreign --	24      Q   So I don't need to pull out my cytotox
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1       strike that.	1       studies and ask you questions about them?
2       Do you understand the general principle that	2       A   You do not.
3       the greater the surface area of a foreign body, the	3       Q   All right. Well, that saved us some time.
4       greater inflammatory response?	4       But leaching is important, right?
5       MR. HUTCHINSON: Object to form.	5       MR. HUTCHINSON: Object to form.
6       THE WITNESS: I've read something along	6       Q (By Mr. Thornburgh) It's an important issue,
7       those lines along the way, yes.	7       right?
8       Q (By Mr. Thornburgh) And you understand that	8       MR. HUTCHINSON: Important to what,
9       the mesh devices have a significantly greater surface	9       Counsel?
10      area than a suture, right?	10      Q (By Mr. Thornburgh) That you considered in
11      MR. HUTCHINSON: Object to form.	11      this case?
12      THE WITNESS: Yeah, in general, sure.	12      A   What do you mean by "important"?
13      Q (By Mr. Thornburgh) Do you know how many	13      Q   It's important in -- did you look at any
14      meters of mesh -- of Prolene sutures are knitted and	14      documents that discuss leaching of the additives,
15      weaved -- or knitted within the TVT device?	15      including the antioxidants?
16      A   It's a -- I haven't done it. It's a simple	16      A   Well, I know that they can be extracted in
17      calculation, but I don't know. I haven't done it.	17      formalin, if that's what you're asking me.
18      Q   You're not suggesting that a single suture	18      Q   Did you look at any studies that showed that
19      would have the same tissue response as a much larger	19      the antioxidants actually leach -- bloom and leach out
20      piece of mesh, are you?	20      of the TVT device?
21      A   I'm just talking about the Prolene resin, the	21      A   Let's be clear. Blooming and leaching are
22      biocompatibility of the Prolene resin. That's all I'm	22      two separate things, so don't confuse the two.
23      talking about.	23      Q   Blooming occurs during the manufacturing
24      Q   So are you going to limit your opinions to	24      process, right?

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<p>1       A It's been alleged. I've yet to see any  2 definitive data on that, but there's been a few  3 allegations in the documents that blooming has  4 occurred.</p> <p>5       Q And leaching occurs over time inside -- in  6 vivo and leaches into the surrounding tissue of the  7 host, right?</p> <p>8       MR. HUTCHINSON: Object to form.</p> <p>9       THE WITNESS: If you're talking about a  10 mechanism that could be in play or a  11 hypothetical mechanism, yes. If you're  12 defining "leaching," is there any documents  13 that I've reviewed or seen that confirm  14 leaching ever took place in vivo, I have yet  15 to see one document.</p> <p>16       Q (By Mr. Thornburgh) You haven't conducted  17 any...</p> <p>18       (Discussion off the written record.)</p> <p>19       Q (By Mr. Thornburgh) I only have one copy, so  20 I'll just show you. This is the deposition of  21 Dr. Barbolt. You read this, correct?</p> <p>22       A Portions of it, yes.</p> <p>23       Q Do you understand that he was designated by  24 Ethicon as the person most knowledgeable about this</p>	<p>1       ladies and gentlemen of the jury what we mean by  2 leach?"</p> <p>3       Answer: "Leaching means the movement of  4 substances from an implant into the surrounding  5 tissue."</p> <p>6       Do you remember reading that deposition?</p> <p>7       A I do.</p> <p>8       Q And do you have any reason to disagree with  9 Dr. Barbolt?</p> <p>10       MR. HUTCHINSON: Object to form.</p> <p>11       THE WITNESS: I do.</p> <p>12       MR. HUTCHINSON: Hold on just a minute.  13 Object to form. Also object that you haven't  14 shown him the entire document.</p> <p>15       THE WITNESS: I do because I --</p> <p>16       MR. THORNBURGH: He's read the document.</p> <p>17       THE WITNESS: I do because I believe  18 it's based off one study that Mr. Burkley  19 performed. And when I reviewed that data, I  20 was not able to conclude that there was any  21 leaching that took place.</p> <p>22       Q (By Mr. Thornburgh) You think this is based  23 off just the one study?</p> <p>24       A That's the only document that I could loosely</p>
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<p>1       subject?</p> <p>2       A Yes, I know he's a 30(b)(6) witness.</p> <p>3       Q Okay. And you understand that he was working  4 for Ethicon for a number of years, I think two decades,  5 studying Prolene --</p> <p>6       A Yeah, I can't --</p> <p>7       Q -- in sutures and in mesh devices?</p> <p>8       A I can't confirm that number of 20 years off  9 the top of my head, but I understand what you're  10 saying.</p> <p>11       Q Okay. So you haven't -- and Ethicon hasn't  12 showed you any of the internal documents regarding --  13 that showed that the Santanox and the Procol leach out  14 of the mesh, right?</p> <p>15       A Not that I recall.</p> <p>16       MR. HUTCHINSON: Object to form.</p> <p>17       THE WITNESS: Not that I recall.</p> <p>18       Q (By Mr. Thornburgh) Right here on page 360  19 of Dr. Barbolt's January 8th, 2004 deposition, he was  20 asked, "Is it Ethicon's position that the antioxidants  21 in the polypropylene Prolene fibers in TVT can leach  22 from the fiber?"</p> <p>23       Answer: "Yes."</p> <p>24       Question: "And could you explain to the</p>	<p>1       connect his testimony to. If there are others, I'd be  2 happy to see, if you have them.</p> <p>3       Q You haven't seen the other ones, right?</p> <p>4       A No. Do you have some?</p> <p>5       Q I'm asking you, you haven't seen any other  6 studies?</p> <p>7       A You keep asking me that question --</p> <p>8       Q I think I --</p> <p>9       A -- and the answer --</p> <p>10       MR. HUTCHINSON: Excuse me. One at a  11 time. Dr. MacLean, finish answering the  12 question.</p> <p>13       Q (By Mr. Thornburgh) The only one you've seen  14 was the Burkley study, which we'll get to in a  15 minute --</p> <p>16       A Sure.</p> <p>17       Q -- the 1987 study --</p> <p>18       A Uh-huh.</p> <p>19       Q -- but you haven't seen any other studies  20 that addressed or looked at leaching or blooming in the  21 TVT Prolene device?</p> <p>22       A No, not that I recall.</p> <p>23       Q Or the Prolene device, period?</p> <p>24       A Correct, same answer.</p>

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<p>1       Q   And if you turn back to Exhibit No. 9, which 2    is the email with -- attached to it is the John Karl 3    memo, it says -- it lists the additives, right, calcium 4    stearate, DLTDP, Santanox R, Procol LA-10, and CPC 5    pigment"?</p> <p>6       A   Correct.</p> <p>7       Q   Okay. And it says that the calcium stearate 8    is a lubricant to help reduce tissue drag and promote 9    tissue passage. The DLTDP, it says, is an antioxidant 10   to improve long-term storage of resin and fiber to 11   reduce the potential oxidative reaction with 12   ultraviolet light.</p> <p>13      A   That's what it says.</p> <p>14      Q   And is -- have you done any independent work 15    to determine what DLTDP is intended to do in terms of 16   retarding degradation?</p> <p>17      A   Yeah, we've already talked about it.</p> <p>18      Q   Okay.</p> <p>19      A   It's a thioester. It's a secondary 20   antioxidant. It's -- they are designed to be peroxide 21   neutralizing.</p> <p>22      Q   Oh, so the DLTDP is intended to be peroxide 23   neutralizing, right?</p> <p>24      A   Correct.</p>	<p>1       Q   Okay. So in 1991, according to this 2    document, the primary antioxidant, according to you, 3    was reduced from the Prolene resin, correct?</p> <p>4       A   That's what it states, which is great because 5    when you look at the dog study -- excuse me. I 6    misspoke.</p> <p>7       Q   The dog study started before that change?</p> <p>8       A   It did. It did, correct.</p> <p>9       Q   So it's not so great, is it?</p> <p>10      MR. HUTCHINSON: Object to form.</p> <p>11      Argumentative.</p> <p>12      THE WITNESS: Correct. But I will say 13    that the .05 percent is still within the 14   tolerance that's given for the Santanox R and 15   the DLTDP in the formulation that's given 16   below.</p> <p>17      Q   (By Mr. Thornburgh) Before you rendered your 18   opinions in this case, did you know that the -- that 19   Ethicon had reduced the primary antioxidant in the 20   Prolene sutures after the seven-year dog study?</p> <p>21      A   Yes.</p> <p>22      Q   The less antioxidant you have, the more 23   potential for degradation, right?</p> <p>24      A   In theory, sure.</p>
<p style="text-align: center;">Page 171</p> <p>1       Q   Because this says to protect against 2    ultraviolet light.</p> <p>3       A   That's true too.</p> <p>4       Q   And then the Santanox R, an antioxidant to 5    promote stability during compounding and extrusion.</p> <p>6       A   That's what it says.</p> <p>7       Q   It doesn't say that there's an antioxidant 8    that is intended to retard oxidative degradation in 9    vivo for -- as a permanent device?</p> <p>10      A   Correct. And this is not a scientific 11    treatise. This is just a couple of bullet points to 12    describe these antioxidants in general. If you look at 13    the scientific literature, it is crystal clear what 14    those two antioxidants do.</p> <p>15      Q   And do you see any thioesters? Oh, I think 16    you said earlier that the thioester is the DLTDP?</p> <p>17      A   Correct.</p> <p>18      Q   I just want to show you real quick on the 19    same exhibit, it says, "The additive package in use 20    today is the same as was used in the original 21    formulation for years. In addition, in 1991 the 22    Santanox level were reduced slightly by .05 percent."</p> <p>23      Do you see that?</p> <p>24      A   I was trying to recall it. I see that.</p>	<p style="text-align: center;">Page 173</p> <p>1       Q   Do you think that Santanox R and DLTDP 2    protect the Prolene fibers in the TVT from degradation 3    in pertuity [sic]?</p> <p>4       MR. HUTCHINSON: Object to form.</p> <p>5       THE WITNESS: Well, let's look at the 6    data. So if you look at the seven-year dog 7    study and you --</p> <p>8      Q   (By Mr. Thornburgh) Which is before the 9    reduction?</p> <p>10      MR. HUTCHINSON: Dan, no.</p> <p>11      Dr. MacLean -- Dr. MacLean --</p> <p>12      THE WITNESS: Yeah, sure.</p> <p>13      MR. HUTCHINSON: -- I need you to finish 14    your answer, please.</p> <p>15      THE WITNESS: Yeah. If you look at the 16    seven-year dog study, the trend is clear with 17    the physical properties that have been 18    tested. There's no degrading taking place. 19    There's no trend downward in any of that 20    data. So we know that it's lasting for seven 21    years and the trend is positive.</p> <p>22      So if you extrapolate a positive trend, 23    that just means that those physical 24    properties continue to get better over time.</p>

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<p>1        So there's no -- there's no indication that  2        over the decades that this thing may be in a  3        body, that you're going to have physical  4        property reduction like you're -- like you're  5        trying to -- like folks are trying to suggest  6        with this oxidation theory.</p> <p>7        Q (By Mr. Thornburgh) The dog study that  8        you're referencing started before Ethicon reduced the  9        Santanox level, right?</p> <p>10      A It did, correct.</p> <p>11      (Exhibit 10 marked for identification.)</p> <p>12      Q (By Mr. Thornburgh) I'm handing you one of  13        the documents that you reference in your expert report  14        as Exhibit No. 10. Have you reviewed this document?</p> <p>15      A It looks familiar.</p> <p>16      Q It says, "Polypropylene and some polyethylene  17        (PE) resins in their natural state (without additives)  18        are inherently unstable and degrade when exposed to  19        oxygen," right?</p> <p>20      A Correct.</p> <p>21      Q It says, "The degradation is similar to the  22        rusting (or oxidation) of untreated iron in that the  23        polymers change colors to yellow-brown and begin to  24        flake away until the material becomes useless. When</p>	<p>1        necessarily polypropylene, but polymer --  2        A Right.  3        Q -- resins, right? And those are put in there  4        to retard or to slow down the degradation process,  5        right?</p> <p>6        A Correct.</p> <p>7        Q It doesn't stop it completely, does it?  8        A It depends on the useful life of the device.  9        And all the data that we have right now clearly tells  10       us that none of the properties are trending down. None  11       of the important bulk physical properties of the  12       Prolene, none of the important bulk physical properties  13       of the mesh are trending down.</p> <p>14      (Exhibit 11 marked for identification.)</p> <p>15      Q (By Mr. Thornburgh) I'm handing you what's  16        been marked as Exhibit No. 11. This is an internal  17        Ethicon memo dated September 30th, 1987, right?</p> <p>18      A It is.</p> <p>19      Q And it says that -- "IR microscopy of  20        explanted Prolene received from Professor Guidon,"  21        right?</p> <p>22      A Correct.</p> <p>23      Q And this was 1987. This was like a long time  24        ago --</p>
<p style="text-align: center;">Page 175</p> <p>1        polypropylene or PE degrades, chain scission takes  2        place. The physical properties of the polymer  3        deteriorate and its average molecular weight (chain  4        length) decreases, melt flow rate increases and a  5        powdery surface eventually forms." Do you agree with  6        those statements?</p> <p>7        A I think that's a good general description of  8        unstabilized polypropylene and polyethylene in the  9        presence of an oxidizing environment.</p> <p>10      Q It goes on to say in the next paragraph,  11        "Polymer degradation is a natural phenomenon that  12        cannot be totally stopped." Do you agree with that?</p> <p>13      A It's a very general statement. I will tell  14        you that, you know, in theory, theoretically speaking,  15        materials can degrade over time. That's -- you know,  16        everything does. Our skin, for example, right, we shed  17        skin over time. Materials degrade over time. That's  18        all that statement is saying. It's -- I don't know how  19        you apply it to a specific polymer or a specific  20        polymer system.</p> <p>21      Q I mean, but in your experience, you've dealt  22        with antioxidant additives, right?</p> <p>23      A Sure.</p> <p>24      Q That are put into polymer resins, not</p>	<p style="text-align: center;">Page 177</p> <p>1        A It's --  2        Q -- several decades ago?  3        A It was about 28 years ago.  4        Q Twenty-eight years ago. And do you know who  5        Dr. Guidoin is?  6        A Only from what I've read in the files.  7        Q It says, "Samples of Prolene suture carefully  8        removed from human" -- let me ask you this question:  9        Have you -- have you reviewed any publications by  10       Dr. Guidoin, peer-reviewed publications?  11      A I don't recall.  12      Q "Samples of Prolene sutures carefully removed  13        from human vascular graft explants received from  14        Professor Guidoin were examined by IR microscopy as is.  15       A Prolene suture control was examined for comparison."  16      It goes on to talk about how there were -- in  17        the two-year explant, there were no cracks, and in the  18        eight-year explant, there was severe cracking, right?  19      A Correct. That's what it says.  20      Q It says, "Some samples of the eight-year were  21        examined optically. Using a needle, the scratched  22        [sic] surfaces were easily wiped off and deposited on a  23        KBr window. The surface scrapings had the handling and  24        consistency of a waxy snow. The sample was not</p>

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<p>1 conducive to IR microscopy in this form however.  2 Similar treatment with needles on sterile packaged  3 Prolene and the two-year sample generated no  4 scrapings."</p> <p>5 So there were some changes, right, surface  6 changes on this explant that were consistent with a  7 waxy snow?</p> <p>8 A I wouldn't -- I wouldn't characterize them as  9 surface changes, but there was a waxy snow material  10 found on the exterior of the implant.</p> <p>11 Q And we just looked at the document and you  12 agreed that degraded polypropylene becomes powdery,  13 correct?</p> <p>14 MR. HUTCHINSON: Object to form.</p> <p>15 THE WITNESS: Right. I didn't say  16 waxy.</p> <p>17 Q (By Mr. Thornburgh) "The surface scrapings  18 spectra are very different from the bulk spectra, and  19 both types of spectra showed no evidence of the  20 presence of protein," right? Do you see that?</p> <p>21 A Yes.</p> <p>22 Q "The surface scrapings spectra of the  23 eight-year clearly indicated polypropylene."</p> <p>24 So they scraped it off, right, the stuff</p>	<p>1 his name on them, right?</p> <p>2 A Not at this time. Not at this time. He has  3 just joined the company at this time. We're talking  4 about Dr. -- or Mr. Burkley?</p> <p>5 Q He's worked -- he's an employee that has been  6 with Ethicon for a number of years?</p> <p>7 A Presently. Not in 1987.</p> <p>8 Q Okay. Okay. So you don't think he was  9 qualified to render these conclusions?</p> <p>10 A I didn't say that. I was just clarifying  11 when he was employed and how much experience he had  12 and --</p> <p>13 Q Do you know what his position was there?</p> <p>14 A Not specifically. He looks like he's working  15 at the direction of other senior scientists.</p> <p>16 Q He's testing degraded polypropylene 28 years  17 before any of this litigation ever started, right?</p> <p>18 MR. HUTCHINSON: Object to form.</p> <p>19 THE WITNESS: Correct.</p> <p>20 Q (By Mr. Thornburgh) And outside of the  21 courtroom, when he's in his lab working for Ethicon  22 when there's no litigation going on, he writes that  23 "The amount of DLTDP is reduced in the explanted  24 sutures. No DLTDP is observed in the surface scraped</p>
<p style="text-align: center;">Page 179</p> <p>1 scraped off, they tested it using IR microscopy, and  2 it -- and what they scraped off was polypropylene?</p> <p>3 MR. HUTCHINSON: Object to form.</p> <p>4 Compound.</p> <p>5 Q (By Mr. Thornburgh) Right?</p> <p>6 MR. HUTCHINSON: Compound question.</p> <p>7 THE WITNESS: That's what it says.</p> <p>8 Q (By Mr. Thornburgh) And just above that, the  9 first paragraph on the second page of the Exhibit 11,  10 it says, "The surface scrapings were melted at 147 to  11 156 degrees Celsius on the Mettler hot stage. This is  12 the melting range previously observed for oxidatively  13 degraded polypropylene," right?</p> <p>14 A That's what it states.</p> <p>15 Q And you disagree with that, don't you?</p> <p>16 A I do.</p> <p>17 Q The conclusions that were drawn by  18 Dr. Burkley, who was an Ethicon employee -- you  19 understand that, right --</p> <p>20 A I do.</p> <p>21 Q -- an Ethicon scientist, right --</p> <p>22 A He was.</p> <p>23 Q -- and worked for Ethicon for many, many  24 years, you've seen -- you've numerous documents with</p>	<p style="text-align: center;">Page 181</p> <p>1 (cracked regions) of the eight-year explant. The  2 observed DLTDP decreases with implant time."</p> <p>3 In other words, it's leaching out over time,  4 according to Dr. Burkley, right?</p> <p>5 MR. HUTCHINSON: Object to form. It's  6 also an argumentative question, Counsel.</p> <p>7 THE WITNESS: That's what it states, but  8 that's not what the data is telling us. And  9 you cannot use FTIR as a quantitative tool.  10 It's just not -- just not how it works unless  11 you do a significant amount of studies.</p> <p>12 Q (By Mr. Thornburgh) Dr. Burkley --</p> <p>13 A I understand.</p> <p>14 Q -- scientist for Ethicon, is saying --</p> <p>15 A Sure.</p> <p>16 Q -- DLTDP is leaching out over time, right?</p> <p>17 MR. HUTCHINSON: Object to form.</p> <p>18 THE WITNESS: That's what --</p> <p>19 MR. HUTCHINSON: Mischaracterization of  20 the document. Dr. MacLean, go ahead.</p> <p>21 THE WITNESS: That's what Item No. 1 in  22 the conclusions say. I'm telling you that he  23 did not arrive at that conclusion in a  24 scientific manner.</p>

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<p>1       Q (By Mr. Thornburgh) He goes on to say, "No 2       protein is observed in any spectra of the explanted 3       sutures," right? 4       A That's what he says. 5       Q "The surface scraped material from the 6       cracked regions of the eight-year explant has a melting 7       range indicative of degraded polypropylene. The IR 8       spectra of this scraped material is clearly 9       polypropylene." Did I read that correctly? 10      A That's what it says. 11      Q And so you disagree with Dr. Burkley, right? 12      A I do. 13      Q So you disagree with Dr. Wood so far. You 14      disagree with -- 15      A No, no, no. I didn't say I disagree with 16      Dr. Wood the way you're phrasing it. I was saying that 17      there's a second mechanism that they did not address. 18      Q You disagree with Dr. Wood's definitive 19      conclusion? 20      A That's correct. 21      Q You disagree with Dr. Thames, an expert in 22      this case for the defendants? 23      MR. HUTCHINSON: Object to form. 24      THE WITNESS: It's --</p>	<p>1       don't need to talk over each other. Let 2       Dr. MacLean finish his answer, if you 3       remember the question. 4       THE WITNESS: I need to hear the 5       question again. 6       Q (By Mr. Thornburgh) Dr. Barbolt testified 7       that the TVT device undergoes surface degradation, that 8       the surface cracks and peels away from the surface. Do 9       you disagree with Ethicon's scientist, Dr. Barbolt, who 10      is speaking on behalf of Ethicon as the 30(b)(6) 11      witness, that the Prolene in the TVT degrades, 12      surface -- undergoes surface degradation? 13      MR. HUTCHINSON: Object to form. 14      Mischaracterizes the testimony of 15      Dr. Barbolt. 16      THE WITNESS: I disagree with that. 17      MR. HUTCHINSON: Dan, we've been going 18      for about an hour. Let me know when we're at 19      a good spot to take a break. 20      MR. THORNBURGH: Let me finish this line 21      of questioning -- 22      MR. HUTCHINSON: Okay. 23      MR. THORNBURGH: -- and then we'll take 24      a break.</p>
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<p>1       MR. HUTCHINSON: Hey, wait a minute. 2       Object to form. Mischaracterizes the 3       testimony. 4       Q (By Mr. Thornburgh) Right? 5       A It's the same answer I just gave you for 6       Wood. 7       Q You disagree with Dr. Barbolt, right? 8       MR. HUTCHINSON: Same objections. 9       Q (By Mr. Thornburgh) Right? 10      A I -- not the way you're phrasing it, no. 11      Q Do you agree with Dr. Barbolt that the 12      surface layer of the TVT Prolene device degrades in 13      vivo, that the TVT device undergoes surface 14      degradation? 15      MR. HUTCHINSON: Object -- 16      Q (By Mr. Thornburgh) Do you agree or disagree 17      with Dr. Barbolt? 18      MR. HUTCHINSON: Object to form. 19      THE WITNESS: I thought you were talking 20      about the leaching with Dr. Barbolt. 21      MR. THORNBURGH: Well, that's one issue, 22      but he had -- 23      MR. HUTCHINSON: Hey, guys, hey, look, 24      I'm not going to say it again; both of you</p>	<p>1       Q (By Mr. Thornburgh) Dr. Barbolt's 2       January 8th, 2014 deposition, page 409, lines 2 through 3       13. 4       MR. HUTCHINSON: Counsel, do you have a 5       copy for me or the witness? Counsel, do you 6       have a copy for me or the witness? 7       MR. THORNBURGH: No. 8       Q (By Mr. Thornburgh) 409, line 2, question: 9       "And that's Ethicon's position, as a spokesperson for 10      Ethicon, it's Ethicon's position that degradation, 11      surface degradation, can occur, correct?" 12      The witness answers, "Yes." 13      "And this was well known in advance of this 14      statement that the material is not absorbed, nor is it 15      subject to degradation, correct?" 16      "Yes. This was from 1992." 17      Do you disagree with Dr. Barbolt, who is an 18      Ethicon employee, an internal scientist, who was 19      designated by Ethicon as the person most knowledgeable 20      about degradation, a 30(b)(6) witness, who testified 21      that the Prolene in the TVT undergoes surface 22      degradation? 23      A I do. 24      MR. HUTCHINSON: Same objections.</p>

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<p>1       THE WITNESS: I do. I disagree.</p> <p>2       Q (By Mr. Thornburgh) And you understand that</p> <p>3       Dr. Barbolt -- this is 2014 -- Dr. Barbolt had been</p> <p>4       working with the company for a couple decades?</p> <p>5       A That's what it says.</p> <p>6       Q And he was the person who was there in the</p> <p>7       lab working with Prolene sutures and Prolene mesh</p> <p>8       devices, right?</p> <p>9       A Apparently.</p> <p>10      Q And you didn't form an opinion about TVT or</p> <p>11      Prolene until after you were retained by Ethicon in</p> <p>12      this case, correct?</p> <p>13      MR. HUTCHINSON: Object to form.</p> <p>14      THE WITNESS: That's correct.</p> <p>15      Q (By Mr. Thornburgh) And in addition to</p> <p>16      disagreeing with Dr. Barbolt, you also disagree with</p> <p>17      Dr. Burkley?</p> <p>18      A On this document, I do, absolutely.</p> <p>19      Q From his study from 1987, right?</p> <p>20      A Correct.</p> <p>21      MR. THORNBURGH: Want to take a break?</p> <p>22      MR. HUTCHINSON: Yeah. Not long.</p> <p>23      THE VIDEOGRAPHER: We are now going off</p> <p>24      the video record. The time is currently</p>	<p>1       A They did, correct.</p> <p>2       Q And it says, "The biocompatibility of these</p> <p>3       materials has been the subject of investigation of</p> <p>4       several authors," and they list some authors.</p> <p>5       So there were other authors back in the '80s</p> <p>6       who were also looking at Prolene degradation. And</p> <p>7       Jongebloed and his colleagues go on to write that,</p> <p>8       "Nevertheless, there is still no clear explanation of</p> <p>9       the phenomenon one can observe in the pictures,</p> <p>10      although there are strong indications for enzymatic</p> <p>11      reaction [sic] being the cause of the surface changes</p> <p>12      on these materials." Did I read that correctly?</p> <p>13      MR. HUTCHINSON: Object to form.</p> <p>14      MR. THORNBURGH: I'm on the first page</p> <p>15      of Exhibit 12.</p> <p>16      THE WITNESS: And I'm just trying to</p> <p>17      track on which paragraph you just read.</p> <p>18      Q (By Mr. Thornburgh) Second -- see the</p> <p>19      introduction?</p> <p>20      A Yep.</p> <p>21      Q See where they say that they looked at</p> <p>22      Prolene and other sutures that were explanted from the</p> <p>23      human eye?</p> <p>24      A Correct.</p>
<p style="text-align: center;">Page 187</p> <p>1       2:44 p.m. This is the end of Tape No. 3.</p> <p>2       (Recess taken.)</p> <p>3       THE VIDEOGRAPHER: We are now back on</p> <p>4       the video record with Tape No. 4. The time</p> <p>5       is currently 2:59 p.m.</p> <p>6       (Exhibit 12 marked for identification.)</p> <p>7       Q (By Mr. Thornburgh) Doctor, I'm handing you</p> <p>8       what's been marked as Exhibit No. 12. Before we went</p> <p>9       on the break, we were talking about some of the</p> <p>10      internal documents that were done by Ethicon. And</p> <p>11      around the same time period, there were other</p> <p>12      researchers outside of Ethicon who were also analyzing</p> <p>13      Prolene for degradation, right?</p> <p>14      A I believe so.</p> <p>15      Q In fact, Dr. Jongebloed -- I'm not sure if I</p> <p>16      pronounced his name right; it's J-O-N-G-E-B-L-O-E-D --</p> <p>17      published an article called the "Mechanical and</p> <p>18      biomechanical effects of man-made fibres and metals in</p> <p>19      the human eye, a SEM-study," in 1986. Do you recognize</p> <p>20      this study? Have you seen this study before?</p> <p>21      A I have.</p> <p>22      Q And in this study, Jongebloed and his</p> <p>23      colleagues analyzed explanted sutures, including</p> <p>24      Prolene, correct, from human eyes?</p>	<p style="text-align: center;">Page 189</p> <p>1       Q And they say -- he goes on to say, "There is</p> <p>2       no clear explanation of the phenomenon one can observe</p> <p>3       in these pictures, although there are strong</p> <p>4       indications of enzymatic action being the cause of the</p> <p>5       surface changes on these materials."</p> <p>6       So he's just giving a history of sort of what</p> <p>7       the theory back then was in 1987, right?</p> <p>8       MR. HUTCHINSON: Object to form.</p> <p>9       MR. THORNBURGH: 1986 --</p> <p>10      THE WITNESS: That's what he states.</p> <p>11      MR. THORNBURGH: -- right?</p> <p>12      Q (By Mr. Thornburgh) But then he says, you</p> <p>13      know, as a good scientist does, he goes on and says,</p> <p>14      "On the other hand, all kinds of explanations are</p> <p>15      given, such as fixation or drying artifact, mechanical</p> <p>16      damage when the lens and loops are taken out of the</p> <p>17      eye, damage caused by the irradiation in the SEM,</p> <p>18      possible effects of the sterilization agents, UV light,</p> <p>19      et cetera."</p> <p>20      All right, so he's saying maybe there's</p> <p>21      another cause, maybe it's not oxidative degradation</p> <p>22      that's occurring inside these human eyes of these</p> <p>23      Prolene sutures, maybe there's another cause, so let's</p> <p>24      test it.</p>

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<p>1           MR. HUTCHINSON: Object to form.</p> <p>2           Q (By Mr. Thornburgh) Right?</p> <p>3           A He doesn't -- he does not postulate</p> <p>4           oxidation/degradation. He just says enzymatic action.</p> <p>5           Q What else would the enzymatic action be?</p> <p>6           A Could just mean proteins that are actually</p> <p>7           bonding onto the surface.</p> <p>8           Q Have you read this?</p> <p>9           A I've read -- I'm just telling you what -- you</p> <p>10          just asked about a specific passage in the</p> <p>11          introduction, and I'm just -- I'm just reflecting on</p> <p>12          it.</p> <p>13          Q Well, if you've read it, you know that he</p> <p>14          goes on to talk about free radicals and the</p> <p>15          inflammatory response and oxidative degradation.</p> <p>16          A Correct. But that's not what you had just</p> <p>17          cited to me.</p> <p>18          Q Well, okay. "Materials and Methods."</p> <p>19          The Prolene material was part of an open J-lens, and it</p> <p>20          was implanted in a Pakistani patient for one year,</p> <p>21          right?</p> <p>22          A Correct.</p> <p>23          Q See the "Results" section? And it was</p> <p>24          explanted apparently because the patient was having</p>	<p>1           that if it's protein that's forming around the surface</p> <p>2           of the diameter of the fiber, that the diameter would</p> <p>3           increase, right?</p> <p>4           MR. HUTCHINSON: Object to form.</p> <p>5           THE WITNESS: Where do you see his</p> <p>6           diametrical measurements? I know where the</p> <p>7           statement comes from. Where are the</p> <p>8           diametrical measurements that he's referring</p> <p>9           to?</p> <p>10          Q (By Mr. Thornburgh) Are you saying because</p> <p>11          they're not there, you don't believe him?</p> <p>12          MR. HUTCHINSON: Objection. Counsel,</p> <p>13          that's argumentative. Don't do that with</p> <p>14          this witness.</p> <p>15          MR. THORNBURGH: I'm just trying to</p> <p>16          understand if that's what his point is.</p> <p>17          MR. HUTCHINSON: Okay. Well, you can</p> <p>18          ask -- you can ask it that way, but don't --</p> <p>19          Q (By Mr. Thornburgh) Is that -- is that</p> <p>20          the --</p> <p>21          MR. HUTCHINSON: Hey, Dan, you can ask</p> <p>22          it that way, but don't argue with the</p> <p>23          witness.</p> <p>24          Q (By Mr. Thornburgh) Is the position that</p>
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<p>1           complications, right?</p> <p>2           A I believe that's what it says, correct.</p> <p>3           Q So both Prolene loops showed severe</p> <p>4           degradation of the surface layer. And they show some</p> <p>5           pictures. Figure 1, they say, "The irregular cracks in</p> <p>6           this deposit (see arrows) are due to drying, a common</p> <p>7           phenomenon in SEM specimens of inhomogeneous structure.</p> <p>8           Figure 2 shows at high magnification the very regular</p> <p>9           pattern of striations. Some parts of the surface are</p> <p>10          crossed [sic] with a thin deposit, comparable to the</p> <p>11          layer seen in Figure 1. The degradation of the surface</p> <p>12          layer can be observed in more detail in Figure 3. Part</p> <p>13          of the surface layer is detached, exposing the</p> <p>14          subsurface layer, which shows a similar cracking</p> <p>15          pattern (see arrows)."</p> <p>16          He goes on to write, "The fact that the</p> <p>17          subsurface layer shows a similar cracking pattern of</p> <p>18          degradation is a clear indication of biodegradation.</p> <p>19          If the phenomenon we observe were the result of the</p> <p>20          drying of a deposit, then the cracks in it would have a</p> <p>21          much more regular" -- "irregular character, like the</p> <p>22          cracks seen in Figure 1."</p> <p>23          The total diameter of the degraded loop has</p> <p>24          certainly not increased, right? So you would expect</p>	<p>1           you're taking, that this study in 1986 isn't a study</p> <p>2           that can be relied upon, because you don't see</p> <p>3           diametric measurements?</p> <p>4           A Yes. He's making a bold statement about the</p> <p>5           thickness of the cracked layer with respect to the</p> <p>6           original diameter of the fiber, and I would expect that</p> <p>7           data to be in here, yes. That would be scientifically</p> <p>8           sound to put that in there. You're talking about a</p> <p>9           cracked layer that is on the order of a micron. You're</p> <p>10          talking about a fiber diameter that's on the order of</p> <p>11          100 to 150 microns. So, yes, you need to show that</p> <p>12          specific measurement to make that statement.</p> <p>13          Q Did you make any of those measurements? Have</p> <p>14          you ever done that analysis?</p> <p>15          A I've seen other folks try to attempt it, yes.</p> <p>16          Q Have you done it?</p> <p>17          A I have not done it.</p> <p>18          Q If you look at the --</p> <p>19          A But I will tell you it can be done. I mean,</p> <p>20          you can make these discrete measurements. I don't know</p> <p>21          if even if you make them, if you can make that</p> <p>22          connection; but if you're going to make that statement,</p> <p>23          you better have the data to support it.</p> <p>24          Q We're talking about Prolene here, right?</p>

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<p>1 A We are.</p> <p>2 Q The same material in the TTV devices, right?</p> <p>3 A Correct.</p> <p>4 Q And if you look at Figure 1 through 4 of the</p> <p>5 SEMs, that's some significant cracking, right?</p> <p>6 MR. HUTCHINSON: Object to form.</p> <p>7 THE WITNESS: I'd say it looks typical</p> <p>8 cracking from what we've seen over and over</p> <p>9 and over again for the last 20 years of</p> <p>10 documents.</p> <p>11 Q (By Mr. Thornburgh) It is -- it is typical</p> <p>12 because what happens when you -- when you purposely</p> <p>13 degrade it using UV radiation, the TTV mesh that you</p> <p>14 analyzed, it looked very similar to this, didn't it?</p> <p>15 MR. HUTCHINSON: Object to form.</p> <p>16 THE WITNESS: No, it didn't. Let's put</p> <p>17 them side by side.</p> <p>18 MR. THORNBURGH: We'll do that in a</p> <p>19 moment.</p> <p>20 THE WITNESS: Sure.</p> <p>21 Q (By Mr. Thornburgh) So you think that your</p> <p>22 cracks look different than the cracks that we're seeing</p> <p>23 in all these publications for the last 20, 30 years?</p> <p>24 MR. HUTCHINSON: Object to form. It's</p>	<p>1 severe changes on the surface of both. Nonimplanted</p> <p>2 material given the same treatment did not show any</p> <p>3 surface changes when examined in SEM. Nonimplanted</p> <p>4 material soaked in distilled water for a long time,</p> <p>5 dried in air, sputter-coated with gold and examined in</p> <p>6 the SEM under the same conditions, did not show any</p> <p>7 surface changes either. We think the surface changes</p> <p>8 observed in the implanted Prolene are the result of</p> <p>9 biodegradation by enzymatic action of the tissue</p> <p>10 fluids."</p> <p>11 You disagree with this scientist, as well,</p> <p>12 from 1986, right?</p> <p>13 A I do because he's not shown us what the</p> <p>14 chemical composition is, and that's the only way you</p> <p>15 can determine, A, if that cracked layer is</p> <p>16 polypropylene -- or Prolene, rather; and B, if it's</p> <p>17 degraded. He hasn't done any of that in this study.</p> <p>18 Q But if he showed you a chemical composition,</p> <p>19 if he did an FTIR and reported it in this study, you'd</p> <p>20 say, "But there's protein surrounding that fiber,"</p> <p>21 right?</p> <p>22 MR. HUTCHINSON: Object to form.</p> <p>23 THE WITNESS: If there were protein</p> <p>24 surrounding it, I would, yes.</p>
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<p>1 argumentative, mischaracterizes what the</p> <p>2 witness just told you.</p> <p>3 THE WITNESS: They certainly don't look</p> <p>4 like this -- I'll call these concentric or</p> <p>5 repetitive striation cracks that you see in</p> <p>6 the top right-hand corner on Figure 2.</p> <p>7 Q (By Mr. Thornburgh) What about Figure 3?</p> <p>8 A Maybe, maybe some similarities, but...</p> <p>9 Q And Figure 3 is the figure that was described</p> <p>10 here as, "The degradation of the surface layer can be</p> <p>11 observed in more detail in Figure 3."</p> <p>12 A You cannot make an assessment of whether you</p> <p>13 have degraded polypropylene just by looking at SEM</p> <p>14 images, period.</p> <p>15 Q Not only the top layer is cracked, but also</p> <p>16 the layer that's underneath the top layer.</p> <p>17 A Okay. Show me where he's characterized those</p> <p>18 materials. Where is the chemical composition of those</p> <p>19 cracks?</p> <p>20 Q If you go to page 311, it says, "The</p> <p>21 phenomenon observed on the surface of implanted Prolene</p> <p>22 is a topic of interest to several authors, as already</p> <p>23 noted. The Prolene we investigated had remained in the</p> <p>24 eye of a Pakistani patient for one year and showed</p>	<p>1 Q (By Mr. Thornburgh) So under your way of</p> <p>2 thinking, it's impossible to determine whether or not</p> <p>3 an explanted TTV Prolene device degraded in vivo?</p> <p>4 MR. HUTCHINSON: Object to form.</p> <p>5 Mischaracterizes the witness's testimony,</p> <p>6 Counsel.</p> <p>7 THE WITNESS: If you look at our</p> <p>8 staining study, I think it's conclusive. The</p> <p>9 staining study tells you, when you combine it</p> <p>10 with what Dr. Iakovlev has done, that this</p> <p>11 cracked layer is not oxidized Prolene.</p> <p>12 Q (By Mr. Thornburgh) You degraded it through</p> <p>13 UV radiation and it cracked, right?</p> <p>14 A It didn't stain.</p> <p>15 Q Well, we're going to get to that in a moment.</p> <p>16 So you disagree with another set of authors from 1986?</p> <p>17 Jongebloed, right?</p> <p>18 MR. HUTCHINSON: Object to form. Dan,</p> <p>19 that mischaracterizes the testimony.</p> <p>20 Q (By Mr. Thornburgh) You disagree with their</p> <p>21 conclusion without more data that the -- that the</p> <p>22 explanted sutures were degraded?</p> <p>23 A If you're going to -- if you're going to --</p> <p>24 MR. HUTCHINSON: Hold on just a minute.</p>

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<p>1      Object to form.</p> <p>2      THE WITNESS: If you're going to state 3      that a polymer is degraded, you should have 4      molecular weight data that supports that 5      opinion, and he does not. The very 6      definition of degradation is not visual 7      cracks on a photograph or a micrograph, which 8      that is the mistake that researcher after 9      researcher after researcher mistake -- that's 10     the mistakes that they made.</p> <p>11     You need molecular weight data to 12     confirm the true degradation, polymer chain 13     scission. I've broken chains down, I've 14     degraded. That's the definition of "polymer 15     degradation." I need that data. You can't 16     do it through FTIR, you can't do it through 17     just -- through these micrographs that you 18     keep showing me.</p> <p>19     Q (By Mr. Thornburgh) You can do it through 20     melting point?</p> <p>21     A No, you can't.</p> <p>22     Q The melt -- if there's a --</p> <p>23     A I just explained to you --</p> <p>24     MR. HUTCHINSON: Hey, Dan, stop it.</p>	<p>1      oxidatively degraded it, the -- and then you melted it 2      and the melt point was lower than the pristine implant, 3      that melt point change is evidence of oxidative 4      degradation, right, number one?</p> <p>5      A It can be.</p> <p>6      MR. HUTCHINSON: Object.</p> <p>7      Q (By Mr. Thornburgh) And, number two, when 8      you have a decrease in the melt point, that corresponds 9      with a drop in the molecular weight?</p> <p>10     A No, not for the reasons I just told you. I 11     can get a suppression of melt temperature without 12     reducing molecular weight. That is a fundamental tenet 13     that everyone seems to just dismiss. You don't need to 14     have a reduction or a degradation of the polymer just 15     to see lower melt temperatures. I can plasticize the 16     material and still get there. And we know the material 17     is being plasticized based on the seven-year dog study 18     data.</p> <p>19     Q Maybe you didn't understand my question.</p> <p>20     A I think I did.</p> <p>21     Q My question was: If you took a neat Prolene 22     suture or mesh and you intentionally oxidized it 23     without it ever being in the biological environment --</p> <p>24     A Yep.</p>
<p style="text-align: center;">Page 199</p> <p>1      MR. THORNBURGH: I'm --</p> <p>2      MR. HUTCHINSON: No, stop it. No.</p> <p>3      MR. THORNBURGH: Go ahead.</p> <p>4      MR. HUTCHINSON: I want you to finish 5      your answer, and then Dan Thornburgh can ask 6      another question.</p> <p>7      THE WITNESS: Okay.</p> <p>8      MR. HUTCHINSON: But I need you to 9      finish your answer right now.</p> <p>10     THE WITNESS: Okay. My answer is: With 11     regard to melting point, I am telling you it 12     is a scientific fact when polypropylene will 13     be plasticized or with any polymer 14     plasticized, you will reduce its melting 15     temperature. And we know these materials are 16     plasticized in vivo. That is also a 17     scientific fact based on Jordi's work.</p> <p>18     Q (By Mr. Thornburgh) So hold on. I want to 19     understand your opinion.</p> <p>20     A Sure.</p> <p>21     Q Okay. You would agree with me that if you 22     have a -- if you were to take a neat polypropylene, not 23     explanted from the human body, no protein, not in a 24     biological environment, and you degraded it,</p>	<p style="text-align: center;">Page 201</p> <p>1      -- and it -- the surface cracks and you do 2      FTIR and it shows 1740, and then you do melt point and 3      the melt point has dropped, that's evidence of 4      oxidative degradation, number one, right?</p> <p>5      MR. HUTCHINSON: Object to form.</p> <p>6      Q (By Mr. Thornburgh) All those things, right?</p> <p>7      MR. HUTCHINSON: Object to form.</p> <p>8      THE WITNESS: In that hypothetical 9      situation, in the absence of in vivo 10     environment, that's all reasonable.</p> <p>11     Q (By Mr. Thornburgh) And in the same 12     hypothetical situation, then you do a melt point test, 13     thermal analysis, you melt it, the melt point is lower 14     than the pristine sample, that's also evidence of 15     oxidative degradation and it's evidence of a 16     corresponding drop in molecular weight?</p> <p>17     MR. HUTCHINSON: Objection, compound.</p> <p>18     THE WITNESS: I would say implicitly, 19     yes, but you would want to make the molecular 20     weight analysis. But, again, you've excluded 21     the in vivo conditions, which are very, very 22     much in play here.</p> <p>23     And we know the material is not 24     degrading. The molecular weight analysis</p>

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<p>1 tells us that. The tensile data from the  2 seven-year dog study tells us that. There's  3 no hard scientific data that says these  4 Prolene materials are degrading in vivo via  5 oxidation, or any other mechanism, for that  6 matter. These materials are plasticizing,  7 they're becoming tougher, they're improving  8 their flexibility and ductility over time.  9 It's irrefutable. That data is  10 irrefutable.</p> <p>11 Q (By Mr. Thornburgh) In your expert report,  12 Exhibit No. 2, you have a section called  13 "Formaldehyde-Protein Crosslinking," right?</p> <p>14 A I do.</p> <p>15 Q I'm just trying to understand your opinion.  16 So is it your opinion that the cracked layer that we're  17 seeing on the outside of the TVT Prolene fibers in a --  18 in a specimen that was explanted and then put in  19 formalin and then reagents were used to dissolve the  20 tissue, that those cracks were actually from the  21 formaldehyde-protein crosslinking and not from degraded  22 polypropylene?</p> <p>23 A Let's just start with do I think that they're  24 from the crosslinked formaldehyde-protein polymer that</p>	<p>1 those molecules that are diffusing in have carbonyl  2 groups in them. So if I go up to ATR or an IR  3 instrument and I place an in vivo specimen or specimen  4 that was once in vivo and I try to sample it and I get  5 a carbonyl peak, I don't -- that doesn't surprise me  6 because there are carbonyl functionality groups in  7 those molecules that are now inside the fiber. So  8 that's the answer to your first question.</p> <p>9 Q All right.</p> <p>10 A Do you want to ask me the second --</p> <p>11 Q Are you done?</p> <p>12 A I think I'm done.</p> <p>13 Q All right. So for a crosslinked  14 formaldehyde --</p> <p>15 A Okay.</p> <p>16 Q -- if you -- do you agree -- well, let me ask  17 you one for the first question. How long does it take  18 for the crosslinking to occur once the explant is  19 exposed to formalin?</p> <p>20 A Well, it would -- it would start right away,  21 and there's probably some relationship where -- as a  22 function of time, it asymptotes or reaches a point of  23 diminishing return where you actually react it as much  24 as you can based on the available formaldehyde and the</p>
<p style="text-align: center;">Page 203</p> <p>1 we know is forming in the storage, and the answer to  2 that question is yes. If I put a brittle layer, a  3 brittle crosslinked polymer on the outside of these  4 fibers, take it out of the formalin and then dehydrate  5 it in the environment, like we've seen Ethicon do, and  6 they've seen cracks actually appear under those  7 conditions, then yes, the answer is yes, that brittle  8 layer can form cracks under the right environment.</p> <p>9 Q Is that a different opinion than you have  10 regarding -- I can't speak -- plasticization?</p> <p>11 A I don't know if it's different. I would just  12 say it's an additional opinion that I have.</p> <p>13 Q What are the distinctions between  14 plasticization and crosslinked formaldehyde-protein  15 bond?</p> <p>16 A Okay. So let's start with plasticization.  17 So that is the diffusion of small molecules into the  18 fibers and filaments that actually cause the material  19 to experience changes in its physical properties; and  20 in this case, the net effect is all positive, where you  21 have increase in ductility, you have increase in  22 toughness, you have increase in flexibility. That is  23 exactly what the dog study tells us.</p> <p>24 So I'm just saying that -- and by the way,</p>	<p style="text-align: center;">Page 205</p> <p>1 available amount of protein. But that reaction would  2 start right away. But the degree of crosslinking, the  3 amount of crosslinking, that would be a function of  4 time.</p> <p>5 Q And are you aware of some testing that was  6 conducted by Ethicon to determine whether or not the  7 fixative material had some sort of impact on causing  8 the cracking on the surface layer?</p> <p>9 A Yes. I think they did some short-term  10 maybe -- serum dips with formalin testing. I'm just  11 going off memory.</p> <p>12 MR. THORNBURGH: I'm going to have  13 marked as Exhibit No. 13 a memo dated  14 November 13th, 1984.</p> <p>15 (Exhibit 13 marked for identification.)</p> <p>16 Q (By Mr. Thornburgh) This is another internal  17 document from Ethicon, right?</p> <p>18 A It is.</p> <p>19 Q And the subject line is "Fourier  20 transform-infrared examination of Prolene microcrack  21 and photooxidized polypropylene," right?</p> <p>22 A Yes.</p> <p>23 Q Do you see that?</p> <p>24 A I do.</p>

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<p>1       Q   And do you recognize this memo?</p> <p>2       A   I do.</p> <p>3       Q   And do you understand that in this memo, the</p> <p>4       Ethicon scientists were continuing to analyze the</p> <p>5       microcracking that was being observed on their Prolene</p> <p>6       sutures?</p> <p>7       A   Correct.</p> <p>8       Q   And this memo was put together to investigate</p> <p>9       the microcracked Prolene material by three methods of</p> <p>10      infrared examination, and the question that these IR</p> <p>11      examinations try to answer is what is the composition</p> <p>12      of the exterior cracked surface of the explanted</p> <p>13      Prolene sutures.</p> <p>14      In the course of examining the explants, the</p> <p>15      second question addressed is: Do current methods of</p> <p>16      treating the explants (formalin storage and soluene</p> <p>17      treatment to remove protein) produce artifacts in the</p> <p>18      IR results? And that's what you were talking about,</p> <p>19      right? You're talking about soluene or formalin having</p> <p>20      a chemical reaction that produces an artifact on the</p> <p>21      IR, right?</p> <p>22      MR. HUTCHINSON: Object to form.</p> <p>23      THE WITNESS: I'm not quite sure what</p> <p>24      you're asking, if you could just do that</p>	<p>1       there's actually polymerization, crosslinking going on.</p> <p>2       You're physically creating another material that's</p> <p>3       crosslinked that wasn't there in vivo. There's no</p> <p>4       denying that protein plus formaldehyde will polymerize.</p> <p>5       And then there's also moisture uptake and dehydration</p> <p>6       when the sample goes in and when the sample goes out.</p> <p>7       So everything that's happening in formalin is</p> <p>8       so after the fact that you have to look at this data</p> <p>9       very, very carefully. That's what I'm -- that's one of</p> <p>10      the points that I'm making.</p> <p>11      Q   Do you agree with me that that's one of</p> <p>12      the -- the question that Ethicon scientists were</p> <p>13      trying to answer when they conducted these studies on</p> <p>14      November 13th, 1984?</p> <p>15      A   I think that they were just looking at the</p> <p>16      ability to clean with soluene and -- let me just read</p> <p>17      this before I make any more comments.</p> <p>18      I would say they're trying to determine --</p> <p>19      just like it says here, they're trying to determine the</p> <p>20      composition of the exterior cracked surface of the</p> <p>21      explanted Prolene. I think that's what they're</p> <p>22      investigating.</p> <p>23      Q   They're trying to determine whether or not</p> <p>24      the methods of treating the explants, formalin storage</p>
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<p>1       again.</p> <p>2       Q   (By Mr. Thornburgh) Well, this is -- this is</p> <p>3       what your -- you hypothesized --</p> <p>4       A   It's not a hypothesis.</p> <p>5       Q   -- is a -- is work that was done by Ethicon</p> <p>6       in 1984 to determine whether or not IR examinations can</p> <p>7       determine what is the composition of the exterior</p> <p>8       cracked surface of explanted Prolene sutures, and</p> <p>9       whether or not there's an impact of treating the</p> <p>10      samples with formalin storage and soluene treatment,</p> <p>11      right?</p> <p>12      A   Okay. That's what it says, yes.</p> <p>13      Q   And that's what you have theorized in this</p> <p>14      case?</p> <p>15      A   I have just theorized that once you go into</p> <p>16      formalin, you have to be very careful. All of the data</p> <p>17      becomes suspect, and I'll tell you why. When you</p> <p>18      put -- when you put the specimen in formalin, there are</p> <p>19      chemical and physical reactions that are taking place</p> <p>20      that are beyond whatever might have taken place in</p> <p>21      vivo.</p> <p>22      For example, we know that you can extract out</p> <p>23      the antioxidants. Dr. Jordi has proven that to us.</p> <p>24      And we know that there's a chemical reaction going on,</p>	<p>1       and soluene treatment, to remove protein produce</p> <p>2       artifact in the IR results, which is what you've been</p> <p>3       stating or opining about in this case?</p> <p>4       A   What artifacts are you referring to?</p> <p>5       Q   A protein-formaldehyde bond, for example.</p> <p>6       A   Correct.</p> <p>7       Q   That would be an artifact, right, on the IR?</p> <p>8       A   Right.</p> <p>9       Q   And so that's what they're trying to answer,</p> <p>10      right?</p> <p>11      A   Yes. And we see it in the spectrum; we see</p> <p>12      proteins in some of these spectra. I mean, is that</p> <p>13      what we're debating, whether there's actually --</p> <p>14      Q   No, so let's go -- let's see what the deal</p> <p>15      is, okay?</p> <p>16      A   Okay.</p> <p>17      Q   Let's read it. And see how the surface</p> <p>18      pieces of -- the second paragraph on page 2 of Exhibit</p> <p>19      15 [sic], the 1984 internal Ethicon document, says,</p> <p>20      "Pieces of protein were visually observed to adhere to</p> <p>21      the explant surface. A set of experiments was done to</p> <p>22      remove protein from Explants 84-194 and the serum</p> <p>23      coated 5-0 virgin Prolene, and using" -- "and 2 using</p> <p>24      soluene. The explant and suture were then examined by</p>

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<p>1 ATR and microscopy to see if the cracked surface was  2 removed and to determine the surface composition. The  3 ATR spectra show that protein was efficiently removed  4 from the surface of both explant and protein coated  5 virgin Prolene using soluene. No spectral evidence of  6 soluene was observed, indicating that this solvent  7 washed away cleanly with water. Microscopic  8 examination revealed that the cracks remained." Right?</p> <p>9 MR. HUTCHINSON: Let the record reflect  10 this is Exhibit 13 and not 15.</p> <p>11 MR. THORNBURGH: Exhibit 13.</p> <p>12 THE WITNESS: Correct. And let me --  13 okay.</p> <p>14 Q (By Mr. Thornburgh) If you go just above  15 that, it will help answer the question, "What are we  16 talking about here," right? So to determine the -- on  17 page 1, bottom paragraph, "To determine the relative  18 sensitivity of ATR for observing protein, normal  19 production lot Prolene was coated with serum protein.  20 1918-34-1 was dipped for 10 seconds and 1918-34-2 was  21 dipped for 10 minutes. Both sets were dried and  22 examined by ATR and also microscopically by  23 Dr. Matlaga. The spectra clearly showed very strong  24 protein bands along with polypropylene. Figure 6 also</p>	<p>1 the cracked surface, pieces of the explant and pieces  2 of the soluene treated sample were prepared and sent to  3 McCrone Associates for analysis using FTIR.  4 Dr. McDivitt and Burkley also brought these samples to  5 Digilab to have them examined on their micro/IR system.  6 The explant pieces were examined and transmission IR  7 spectra are described in detail below."</p> <p>8 So then we have the IR here, right? "The  9 explant flake, not soluene treated - The transmission  10 IR spectrum showed strong protein bands with normal  11 polypropylene bands as expected. The amide band" --  12 "the amide band at 1760 [sic] was suspiciously broad  13 and might be hiding oxidation bands if present at  14 1720," right?</p> <p>15 A Yep.</p> <p>16 MR. HUTCHINSON: Form.</p> <p>17 Q (By Mr. Thornburgh) So this is what -- this  18 is what you're talking about, right?</p> <p>19 MR. HUTCHINSON: Same objection.</p> <p>20 THE WITNESS: This is not necessarily  21 what I'm talking about. I'm just working  22 through the study with you, so --</p> <p>23 Q (By Mr. Thornburgh) Okay. The protein  24 bands in the -- so Figure 10 shows the Explant 84-194</p>
<p style="text-align: center;">Page 211</p> <p>1 shows a 1730 band which is in the region of oxidized  2 polypropylene. The origin of the band is not  3 understood in this" -- "is not understood in this  4 sample. It does appear, however, in the transmission  5 spectra of serum protein as deposited on NaCl as shown  6 in Figures 3 and 4 and therefore may be related to  7 protein. The coatings were found to be nonuniform and  8 the apparent thickness of the areas that were coated  9 varied between 2 and 4 microns. The ATR surface now  10 appeared to be quite sensitive to protein present on  11 the surface of the suture.</p> <p>12 "Since pieces of the protein were visually  13 observed to adhere to the explant surface, a set of  14 experiments was done to remove protein from explant  15 1894 [sic] and the serum coated 5-0 virgin Prolene and  16 2 using soluene. The explant and suture were examined  17 by ATR and microscopy to see if the cracked surface was  18 removed and to determine the surface composition. The  19 ATR spectra obtained show that protein was efficiently  20 removed from the surface and both explant and protein  21 coated virgin Prolene suture" -- "coated virgin Prolene  22 using soluene. Microscopic examination revealed the  23 cracks remained.</p> <p>24 "To obtain insight into the composition of</p>	<p style="text-align: center;">Page 213</p> <p>1 flake after soluene treatment of the suture. "The  2 protein bands in the transmission spectrum are  3 significantly smaller relative to untreated explant  4 spectra. A shouldering band at 1720 is more clearly  5 visible, indicating possible ketone species."</p> <p>6 Ketone species would be a carbonyl group,  7 right?</p> <p>8 A They would. They would contain carbonyl.</p> <p>9 Q Okay. And then the explant "melted/yellow  10 cap" -- so here we have, "While soluene removes surface  11 protein effectively from microcracked sutures as  12 monitored by ATR, it apparently is not removing protein  13 that has penetrated below the surface of the flakes."</p> <p>14 That's what you're talking about, right?</p> <p>15 MR. HUTCHINSON: Object to form.</p> <p>16 THE WITNESS: I'm not -- no, I'm not  17 convinced that that's what I'm talking about,  18 but keep reading.</p> <p>19 Q (By Mr. Thornburgh) "And is observed by  20 transmission IR. Thus the cracked surface layer  21 appears to be composed of a protein surface beneath  22 which lies oxidized polypropylene penetrated or  23 plasticized by protein."</p> <p>24 This is what you're -- this is your theory,</p>

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<p>1 right?</p> <p>2 MR. HUTCHINSON: Object to form.</p> <p>3 THE WITNESS: That's not my theory. I</p> <p>4 just need a minute. I want to regroup on my</p> <p>5 thinking on this document.</p> <p>6 Q (By Mr. Thornburgh) They're testing your</p> <p>7 theory out?</p> <p>8 MR. HUTCHINSON: Counsel.</p> <p>9 THE WITNESS: Okay, so my --</p> <p>10 Q (By Mr. Thornburgh) Okay. So they do a</p> <p>11 number of studies to see if protein is getting trapped</p> <p>12 underneath, if formaldehyde is reacting with the</p> <p>13 protein creating some sort of FTIR or IR artifact. And</p> <p>14 they conclude after they run all these different</p> <p>15 studies that you've just reviewed -- you see right</p> <p>16 here, it says -- very top of page 4, ETH.MESH.15958339,</p> <p>17 "The series of polypropylene film experiments were done</p> <p>18 to: Characterize oxidized polypropylene; characterize</p> <p>19 protein on polypropylene; verify that formalin does not</p> <p>20 react or alter the polypropylene explants; determine if</p> <p>21 soluene removed protein efficiently and washed away</p> <p>22 cleanly; determine if soluene causes chemical change to</p> <p>23 the explants; compare experimentally prepared films to</p> <p>24 the explants."</p>	<p>1 through 6? We just did. I thought we'd --</p> <p>2 A No, you did.</p> <p>3 Q -- go into the results.</p> <p>4 A You did.</p> <p>5 Q Why don't we go to the results?</p> <p>6 A I'd like to go through 1 through 6 first.</p> <p>7 Q Okay. The purpose of the study was to</p> <p>8 characterize oxidized polypropylene, right?</p> <p>9 A Fine, let's stop there. So first of all,</p> <p>10 this is polypropylene film, not Prolene. And all</p> <p>11 they've done in No. 1 is they've oxidized</p> <p>12 polypropylene. Okay, fine.</p> <p>13 Q The second was to characterize protein on</p> <p>14 polypropylene. That's something that you --</p> <p>15 A Sure, let me --</p> <p>16 Q This is something --</p> <p>17 A Right.</p> <p>18 Q -- this is data points that you'd want to</p> <p>19 consider, right?</p> <p>20 MR. HUTCHINSON: Okay, guys, one at a --</p> <p>21 one at a time.</p> <p>22 THE WITNESS: Yes, I want to consider</p> <p>23 it, and I have considered it. We know for a</p> <p>24 fact that protein is on the Prolene mesh when</p>
<p style="text-align: center;">Page 215</p> <p>1 That's what we're talking about, right?</p> <p>2 That's a study that you'd want to know and you'd want</p> <p>3 to consider when formulating your opinions in this case</p> <p>4 that what we're seeing on IR spectra and all of these</p> <p>5 studies is something other than oxidation?</p> <p>6 MR. HUTCHINSON: Object -- hold on just</p> <p>7 a minute. Object to form. Dan, I'm not real</p> <p>8 sure what your question was. It was -- in</p> <p>9 all honesty, it was multiple questions.</p> <p>10 MR. THORNBURGH: Okay.</p> <p>11 MR. HUTCHINSON: So what is the --</p> <p>12 Q (By Mr. Thornburgh) The purpose of the --</p> <p>13 MR. HUTCHINSON: -- what is the</p> <p>14 question?</p> <p>15 Q (By Mr. Thornburgh) The purpose of this</p> <p>16 study was to test the theory that you've offered in</p> <p>17 this case?</p> <p>18 A Okay, fine. Let's go -- let's go through --</p> <p>19 MR. HUTCHINSON: Object to form.</p> <p>20 A -- let's go through 1 through 6 and see if we</p> <p>21 can get on the same page.</p> <p>22 Q Okay.</p> <p>23 A All right.</p> <p>24 Q Characterize -- so you want to go through 1</p>	<p style="text-align: center;">Page 217</p> <p>1 it comes out of the body. We know that.</p> <p>2 Q (By Mr. Thornburgh) The No. 3 purpose of the</p> <p>3 study was to verify that formalin does not react or</p> <p>4 alter the Prolene [sic] explants. It's a good data</p> <p>5 point to have, right?</p> <p>6 MR. HUTCHINSON: Object.</p> <p>7 Mischaracterizes the document.</p> <p>8 THE WITNESS: Correct, it does</p> <p>9 mischaracterize the document. All they've</p> <p>10 done here is they've dipped it in --</p> <p>11 Q (By Mr. Thornburgh) The purpose of the</p> <p>12 study -- I'm just --</p> <p>13 MR. HUTCHINSON: No, I'm sorry.</p> <p>14 Q -- reading of the study.</p> <p>15 MR. HUTCHINSON: Dan, stop. I'm telling</p> <p>16 you to stop. Dr. MacLean --</p> <p>17 MR. THORNBURGH: No. Hold on. Hold on.</p> <p>18 No, you know what, Chad --</p> <p>19 MR. HUTCHINSON: -- you can finish your</p> <p>20 answer.</p> <p>21 MR. THORNBURGH: You know what, Chad, my</p> <p>22 question was, the No. 4 purpose that's listed</p> <p>23 here was to determine if soluene removed</p> <p>24 protein efficiently and washed away</p>

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<p>1 cleanly.</p> <p>2 MR. HUTCHINSON: You can -- you can read</p> <p>3 the transcript. That wasn't your question.</p> <p>4 MR. THORNBURGH: Okay. My question was</p> <p>5 to verify --</p> <p>6 MR. HUTCHINSON: But my point --</p> <p>7 MR. THORNBURGH: -- that formalin does</p> <p>8 not react or alter the polypropylene</p> <p>9 explants.</p> <p>10 MR. HUTCHINSON: My point is to let</p> <p>11 Dr. MacLean finish answer your question, then</p> <p>12 ask another one.</p> <p>13 MR. THORNBURGH: He's not answering my</p> <p>14 question.</p> <p>15 THE WITNESS: I'm trying to.</p> <p>16 MR. THORNBURGH: You're not.</p> <p>17 Q (By Mr. Thornburgh) My question is: One of</p> <p>18 the studies that are identified in 1 through 6 here was</p> <p>19 to verify that formalin does not react or alter the</p> <p>20 polypropylene explants. That's what it says, right?</p> <p>21 MR. HUTCHINSON: Object to form.</p> <p>22 Q (By Mr. Thornburgh) Did I read it</p> <p>23 accurately?</p> <p>24 A You did. But we're not talking about the</p>	<p>1 it -- is it affecting the polypropylene</p> <p>2 itself, the explants? This data tells us</p> <p>3 not, and I have no reason not to believe it,</p> <p>4 and I think it's some irrelevant.</p> <p>5 Q (By Mr. Thornburgh) So far I'm -- all I've</p> <p>6 done so far is read to you the purposes. We haven't</p> <p>7 even looked at the conclusions yet.</p> <p>8 A Right. Fine. But I'm telling you those</p> <p>9 purposes are fairly innocuous and irrelevant to what</p> <p>10 we're trying -- what the heart of the matter is.</p> <p>11 Q The other -- the other purpose, No. 5, was to</p> <p>12 determine if soluene causes chemical change to the</p> <p>13 explants; and No. 6 was to compare experimentally</p> <p>14 prepared film to the explants.</p> <p>15 A Okay.</p> <p>16 Q Did I read all that correctly?</p> <p>17 A You did. Let's -- can we just talk about 5?</p> <p>18 Because I don't think we're on the same page with</p> <p>19 soluene. Do you know what -- do you know what soluene</p> <p>20 is?</p> <p>21 Q It's a fixative.</p> <p>22 A It is not a fixative. It is a solution to</p> <p>23 clean tissue. The fixative here is -- is formalin.</p> <p>24 Q Formalin, right. They used soluene to clean</p>
<p style="text-align: center;">Page 219</p> <p>1 polypropylene explants. I'm talking about the tissue</p> <p>2 that's sitting on top of the polypropylene explants.</p> <p>3 Q That's what they're talking about, that's --</p> <p>4 A Yes, for a study that --</p> <p>5 MR. HUTCHINSON: Hey, Dan, hey, look,</p> <p>6 I'm going to stop this deposition if you guys</p> <p>7 keep on talking over each other.</p> <p>8 MR. THORNBURGH: I'm just trying --</p> <p>9 MR. HUTCHINSON: The witness is entitled</p> <p>10 to finish answering his question, and please</p> <p>11 let him do that.</p> <p>12 THE WITNESS: Ten seconds and ten</p> <p>13 minutes dipped is not the same as being in an</p> <p>14 in vivo environment for months, if not years,</p> <p>15 period. So you can't extrapolate these. And</p> <p>16 I don't disagree with this statement that</p> <p>17 they're saying, by the way, that the formalin</p> <p>18 in this study is not interacting with the</p> <p>19 polypropylene explants.</p> <p>20 I'm telling you that the -- it is a --</p> <p>21 it is a fundamental fact of formalin fixation</p> <p>22 that when I take a tissue with protein</p> <p>23 obviously in it and I put it in formalin, it</p> <p>24 fixes, it crosslinks. That's all. Does</p>	<p style="text-align: center;">Page 221</p> <p>1 the tissue that was --</p> <p>2 A Correct.</p> <p>3 Q -- preserved in formalin?</p> <p>4 A Correct.</p> <p>5 Q Yeah, so I --</p> <p>6 A It's okay.</p> <p>7 Q -- I misstated it.</p> <p>8 A That's okay. I want to make sure we</p> <p>9 understood what that -- what that was telling us.</p> <p>10 Q Which is -- which is an important data point</p> <p>11 to consider, right?</p> <p>12 A Sure, it tells us the soluene is not</p> <p>13 negatively interacting with the explant in this</p> <p>14 specific short-term study. And I will tell you that</p> <p>15 the statement where it says that soluene effectively</p> <p>16 cleans is false. If you look at the FTIR data on page</p> <p>17 ending in 346 for Bates number, it's Figure 7, there</p> <p>18 are clearly, in my opinion, protein peaks. They are</p> <p>19 subtle, but there are protein peaks here, and we have</p> <p>20 OH stretch over here at 3300. There's evidence that</p> <p>21 all the protein did not get cleaned away, but that's</p> <p>22 somewhat off topic.</p> <p>23 Q So just let's go through and see what their</p> <p>24 conclusions were, okay?</p>

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<p>1       A    Sure.</p> <p>2       Q    "From the spectra generated and comparisons</p> <p>3       to the ATR and FTIR microscope spectra presented</p> <p>4       earlier, the following conclusions are made:</p> <p>5       Unstabilized polypropylene is relatively easy to</p> <p>6       photooxidize; photooxidized polypropylene exhibits a</p> <p>7       number of species based on IR absorption frequencies,"</p> <p>8       right? We talked about those, some of the carbonyl</p> <p>9       groups that demonstrate polypropylene degradation due</p> <p>10      to the oxidative pathway, right?</p> <p>11      A    Yep, as long as -- as long as you and I</p> <p>12      understand that they've used the word "polypropylene"</p> <p>13      in 1 and 2 and not Prolene.</p> <p>14      Q    Okay. Let's continue to read this, okay?</p> <p>15      "Formalin solution appears to have little effect on the</p> <p>16      oxidized polypropylene surface and no effect on the</p> <p>17      protein removal with soluene," right?</p> <p>18      A    Yep.</p> <p>19      Q    So they're saying they're pretty -- that</p> <p>20      the -- they're easily able to remove protein with</p> <p>21      the -- with the soluene</p> <p>22      A    After 10 seconds -- after 10 seconds and 10</p> <p>23      minutes of laboratory composure, correct.</p> <p>24      Q    "No differences were noted between protein</p>	<p>1       Q    So they're showing that these explanted</p> <p>2       materials that are treated with formalin and then</p> <p>3       subsequently cleaned showed oxidative bands of 1720</p> <p>4       that were able to be observed and the protein bands</p> <p>5       were able to be reduced through the soluene treatments,</p> <p>6       right?</p> <p>7       MR. HUTCHINSON: Object to form.</p> <p>8       THE WITNESS: The oxidation was induced</p> <p>9       on the -- on the polypropylene samples.</p> <p>10      Q    (By Mr. Thornburgh) Yeah, I get that.</p> <p>11      A    Okay.</p> <p>12      Q    They're trying to prove a point here.</p> <p>13      MR. HUTCHINSON: Dan, stop arguing with</p> <p>14      the witness. Do you understand me?</p> <p>15      Q    (By Mr. Thornburgh) They're trying --</p> <p>16      MR. HUTCHINSON: Dan, do you understand</p> <p>17      me?</p> <p>18      MR. THORNBURGH: I hear you.</p> <p>19      MR. HUTCHINSON: All right, well, good.</p> <p>20      I want you to understand me. Please do</p> <p>21      not -- please do not argue with the witness,</p> <p>22      okay?</p> <p>23      MR. THORNBURGH: I'm just -- I'm trying</p> <p>24      to -- I'm not trying to be -- I'm not trying</p>
<p style="text-align: center;">Page 223</p> <p>1       coated films that were subsequently oxidized and</p> <p>2       oxidized films that were protein coated, even after</p> <p>3       soluene treatment," right?</p> <p>4       MR. HUTCHINSON: Objection.</p> <p>5       Q    (By Mr. Thornburgh) That's what it says?</p> <p>6       MR. HUTCHINSON: Are you asking what</p> <p>7       that document says?</p> <p>8       Q    (By Mr. Thornburgh) That's what it says,</p> <p>9       correct?</p> <p>10      A    That's what it states. That's what No. 4</p> <p>11      states.</p> <p>12      Q    And then No. 5, "The soluene treatment not</p> <p>13      only removes surface protein but also alters the</p> <p>14      oxidized polypropylene surface. The surface shows</p> <p>15      mostly anionic or salt (COO) species with some trace</p> <p>16      amounts of ketone and acid species remaining. Lower</p> <p>17      molecular weight species of the oxidized polypropylene</p> <p>18      appear to have been removed with the protein. These</p> <p>19      observations were noted only on the polypropylene</p> <p>20      films. Spectra of soluene treated explants generally</p> <p>21      have been shown to" -- "have shown a retained oxidation</p> <p>22      band at 1720 yet reduced protein bands." Did I read</p> <p>23      that correctly?</p> <p>24      A    You did.</p>	<p style="text-align: center;">Page 225</p> <p>1       to be a jerk. I'm just trying to have a</p> <p>2       conversation with you.</p> <p>3       MR. HUTCHINSON: I understand that, but</p> <p>4       your face is all red, your ears are turning</p> <p>5       red. What I'm asking you to do is not argue</p> <p>6       with the witness. Do you understand me?</p> <p>7       MR. THORNBURGH: I hear you.</p> <p>8       MR. HUTCHINSON: Okay.</p> <p>9       MR. THORNBURGH: I'm not trying to be</p> <p>10      disrespectful.</p> <p>11      MR. HUTCHINSON: Thank you.</p> <p>12      Q    (By Mr. Thornburgh) I'm just trying to go</p> <p>13      over this, what I think is an important study that was</p> <p>14      done by Ethicon in 1984 which tested your theory and</p> <p>15      reached a conclusion that contradicts what you're --</p> <p>16      A    That's patently not true. It is not</p> <p>17      contradicting anything I've said. At the end of the</p> <p>18      day, this document is basically just telling me that</p> <p>19      soluene does not have any effect -- when you clean a</p> <p>20      fiber or film it with soluene, it doesn't have any</p> <p>21      negative effect on the actual polypropylene itself.</p> <p>22      That's all this document ultimately tells me at the end</p> <p>23      of the day.</p> <p>24      And any type of connection you're trying to</p>

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<p>1 make between tissue existence and tissue removal, it  2 all has to be tempered by the fact that the samples  3 were only dipped inside of these serum proteins for 10  4 minutes and 10 seconds respectively. So there's  5 just -- there's not a lot here. In other words, you  6 know, I don't know where we're going with this  7 conversation, but it does not dispute the fact that you  8 get a crosslinked polymer long-term in formalin.</p> <p>9 Q Which is not on the -- not on the 10 seconds.  10 How long does it take?</p> <p>11 A You said --</p> <p>12 Q When I asked you before, you said it was  13 immediate.</p> <p>14 A You could certainly have had some  15 crosslinking at 10 seconds and 10 minutes, but it  16 wasn't fixed enough to really have much of an effect.  17 And the soluene washing it away rather readily, I think  18 is evidence of that. I just don't -- I don't take a  19 lot of stock in this in terms of it disputing that a  20 known fact, which is a crosslinked polymer, takes place  21 inside a formalin fixed storage.</p> <p>22 Q You'd agree with me that the conclusions that  23 they reach are different than those that you --</p> <p>24 A No, I would not agree with you. I would not</p>	<p>1 monomer that's inside the formalin solution. They  2 chemically react, they crosslink, and they make some  3 they make a proteinaceous crosslinked polymer on the  4 outside of the fiber.</p> <p>5 Q So no change in the molecular weight?</p> <p>6 A Of the Prolene, no. It's separate from that.</p> <p>7 Q Okay.</p> <p>8 A We're talking about a layer of material  9 that's actually building and developing inside the  10 formalin solution.</p> <p>11 MR. HUTCHINSON: Now let's take about a  12 five-minute break.</p> <p>13 MR. THORNBURGH: Sure.</p> <p>14 MR. HUTCHINSON: Good.</p> <p>15 THE VIDEOGRAPHER: We are now going off  16 the video record. The time is currently  17 3:46 p.m.</p> <p>18 (Recess taken.)</p> <p>19 THE VIDEOGRAPHER: We are now back on  20 the video record. The time is currently  21 3:53 p.m.</p> <p>22 Q (By Mr. Thornburgh) Doctor, in your expert  23 report, you cite to the dog study and analyze the dog  24 study, right?</p>
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<p>1 agree with you.</p> <p>2 Q Okay. Do you disagree -- you disagree with  3 the conclusions that they reached?</p> <p>4 A I just stepped you through my interpretation  5 of the conclusions, and I think that they're innocuous  6 and off topic.</p> <p>7 Q Do you disagree with the conclusions that  8 they reached?</p> <p>9 MR. HUTCHINSON: Objection. Been asked  10 and answered.</p> <p>11 THE WITNESS: I just -- same answer.</p> <p>12 Q (By Mr. Thornburgh) You didn't answer my  13 question.</p> <p>14 A I did. I stepped you through them. I'm  15 telling you that they're innocuous, they're off topic.  16 I don't agree or disagree with them.</p> <p>17 Q When formaldehyde or formalin is used and the  18 formaldehyde crosslinking occurs, does that increase or  19 decrease the molecular weight?</p> <p>20 A Of what?</p> <p>21 Q Of the Prolene explant.</p> <p>22 A It does not have any effect on the molecular  23 weight of the Prolene material. The crosslinking  24 that's taking place is proteins and formaldehyde</p>	<p>1 A Correct.</p> <p>2 Q So let's talk about the dog study for a  3 little bit, all right?</p> <p>4 A Okay.</p> <p>5 Q That study was started in 1985; is that  6 correct?</p> <p>7 A That is correct.</p> <p>8 Q And it lasted for seven years, right?</p> <p>9 A It did.</p> <p>10 Q It was supposed to be ten years, but it  11 lasted seven, right?</p> <p>12 A Correct, it did.</p> <p>13 Q And in that study, dogs were implanted in  14 their hearts with different suture materials, right?</p> <p>15 A Correct.</p> <p>16 Q Prolene was one of those materials that was  17 tested?</p> <p>18 A Correct.</p> <p>19 Q And PVDF was another one, correct?</p> <p>20 A Yes, it was.</p> <p>21 MR. HUTCHINSON: Excuse me, he may be  22 trying to find -- are you trying to find the  23 dog study?</p> <p>24 THE WITNESS: I'm good.</p>

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<p>1           MR. THORNBURGH: I've got --</p> <p>2           MR. HUTCHINSON: Okay.</p> <p>3           MR. THORNBURGH: I've got exhibits here.</p> <p>4           I can --</p> <p>5           THE WITNESS: Yeah, either way, I'm</p> <p>6           good.</p> <p>7           (Discussion off the written record.)</p> <p>8           (Exhibit 14 marked for identification.)</p> <p>9           Q (By Mr. Thornburgh) So let's look at the --</p> <p>10          I have the two-year dog study right now. Let's just</p> <p>11          look at that and see -- it gives us a little bit of a</p> <p>12          summary. Marked as Exhibit 14 a two-year dog study.</p> <p>13          September 20th, 1988.</p> <p>14          So in this dog study, am I correct that the</p> <p>15          test materials were Prolene size 5-0 and PVDF size 5-0</p> <p>16          and then Ethicon and Novafil of the same size?</p> <p>17          A    Correct.</p> <p>18          Q    And have you reviewed the protocol in this</p> <p>19          study?</p> <p>20          A    I have.</p> <p>21          Q    And it's listed -- if you go to ETH.MESH</p> <p>22          No. 11336075 of Exhibit 14, part of the protocol says</p> <p>23          that after the explantation -- after explantation, the</p> <p>24          explant sample is immediately -- "Immediately after</p>	<p>1           the six-year 10-and-a-half month period, and the</p> <p>2           seven-year period, right?</p> <p>3           A    Correct.</p> <p>4           Q    And different techniques were used to analyze</p> <p>5           the mesh materials during parts of -- or different --</p> <p>6           during different intervals of the 10-year study?</p> <p>7           A    Correct.</p> <p>8           (Exhibit 15 marked for identification.)</p> <p>9           Q (By Mr. Thornburgh) Marked as Exhibit No. 15</p> <p>10          the five-year report from the 10-year dog study.</p> <p>11          Okay. And again, at this interval, the</p> <p>12          sutures were explanted and analyzed, right?</p> <p>13          A    Correct.</p> <p>14          Q    And if you look at page 2 of the report of</p> <p>15          Exhibit 15, ETH.MESH.11336475, it says "SEM of PDVF</p> <p>16          Explants," that there were no cracks or abrasions found</p> <p>17          in any of the explants at five years, right? Am I</p> <p>18          correct?</p> <p>19          A    Yeah, I'm just confirming the -- yes,</p> <p>20          correct.</p> <p>21          Q    Do you know what -- you know what PVDF is,</p> <p>22          right?</p> <p>23          A    I do.</p> <p>24          Q    Okay. And PVDF is another polymer?</p>
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<p>1           explantation, one strand of each sample was randomly</p> <p>2           selected and without being allowed to dry placed in a</p> <p>3           capped, properly labeled test tube containing sterile</p> <p>4           deionized water," right?</p> <p>5           A    Correct.</p> <p>6           Q    The labeling -- I'm sorry. The other five</p> <p>7           strands of each sample would be examined for surface</p> <p>8           damage as described by Ethicon's finished goods</p> <p>9           specifications, correct?</p> <p>10          A    Correct.</p> <p>11          Q    So in this case, they would take a random</p> <p>12          sample and they would immediately -- once they</p> <p>13          explanted it, they would immediately put it in sterile</p> <p>14          deionized water and take it up for sample testing,</p> <p>15          right?</p> <p>16          A    Correct.</p> <p>17          Q    So it wouldn't -- wasn't put into</p> <p>18          formaldehyde, right?</p> <p>19          A    Correct.</p> <p>20          Q    It wasn't put into formalin; it was just put</p> <p>21          into deionized water?</p> <p>22          A    Correct.</p> <p>23          Q    And this study was going to be -- was looked</p> <p>24          at at the two-year period, the five-year period, and</p>	<p>1           A    Fluorinated polymer, correct.</p> <p>2           Q    Uh-huh. And Ethicon -- have you looked at</p> <p>3           studies by Ethicon or internal documents by Ethicon</p> <p>4           where they were considering replacing Prolene with</p> <p>5           PVDF?</p> <p>6           A    I know -- yes, I've seen some memos that talk</p> <p>7           about the alternative material candidates.</p> <p>8           Q    And in this dog study, at the five-year mark,</p> <p>9           the PVDF remained without cracks, but the explanted</p> <p>10          sutures from the Prolene explants -- sorry, on explants</p> <p>11          from dogs 212 and 218, a few cracks -- cracked areas</p> <p>12          were observed. Both of these sutures came out of</p> <p>13          Site 4, right?</p> <p>14          MR. HUTCHINSON: Object to form.</p> <p>15          THE WITNESS: Correct.</p> <p>16          Q (By Mr. Thornburgh) And so the conclusion</p> <p>17          that was drawn by Ethicon's scientists was that after</p> <p>18          five years in vivo, the PVDF 5-0 suture was the only</p> <p>19          explanted material from five dogs which did not show</p> <p>20          any surface damage due to degradation. Out of the</p> <p>21          seven Prolene sutures, two revealed cracking, right?</p> <p>22          A    That's what it says.</p> <p>23          Q    And then again on the next page, page 3, it</p> <p>24          says the Prolene suture intact at two year -- at the</p>

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<p>1 two-year point showed signs of degradation at five  2 years, and that the only intact surface after five  3 years was the PVDF explants, correct?</p> <p>4 A Correct. But they're equating signs of  5 degradation with just visual observations of crack.</p> <p>6 Q Well, do you -- do you disagree with that  7 conclusion in 1990 by Ethicon's scientists?</p> <p>8 A If you're interpreting the word "degradation"  9 as degrading -- degradation of the polymer, I'm  10 absolutely disagreeing with it.</p> <p>11 Q And there are some images of the explanted  12 sutures which show degradation -- which show cracking?  13 I'm sorry.</p> <p>14 A They show surface cracking, correct.</p> <p>15 Q That's on ETH.MESH.11336483?</p> <p>16 A Correct.</p> <p>17 Q And you don't believe that's degraded  18 polypropylene -- or degraded Prolene, correct?</p> <p>19 A Correct.</p> <p>20 Q What is your opinion as to the surface  21 morphology that's being observed on the SEMs?</p> <p>22 A I'm not sure I understand your question.</p> <p>23 Q Do you have an opinion as to what is the  24 cracked layer that is observed on the SEMs?</p>	<p>1 the research that's been done, there's variance of this  2 crack pattern, there's variance of degree of cracking,  3 so I would not use that word "similar." They both have  4 circumferential cracks, and I'd leave it at that.</p> <p>5 Q And the study went on and at 10 years and --  6 or six years and 10-and-a-half months, a dog died and  7 they analyzed this dog just prior to the seven-year  8 interim period, right?</p> <p>9 A Correct.</p> <p>10 (Exhibit 16 marked for identification.)</p> <p>11 Q (By Mr. Thornburgh) I'm handing you what's  12 been marked as 16. Let me ask you a question. In your  13 expert report, when you are talking about some of the  14 characteristics of polypropylene, Exhibit 2, page 12,  15 you say that -- you have a "Molecular Weight" section  16 and you say that, "During synthesis, polypropylene  17 monomers are converted into polypropylene  18 macromolecules of differing lengths. The lengths of  19 polymeric chains are defined by the number average (<math>M_n</math>)  20 and weight average (<math>M_w</math>) molecular weights. Typical  21 molecular weight values for commercial polypropylene  22 vary from 222,000 [sic] to 700,000 g" -- what's that,  23 grams per mole --</p> <p>24 A Grams per mole, correct.</p>
<p style="text-align: center;">Page 235</p> <p>1 A Yeah, of course I do.</p> <p>2 Q What's your opinion?</p> <p>3 A Let me tell you what we -- what we know. We  4 know that the cracked layer is not oxidized Prolene.  5 We know the cracked layer is not Prolene. And we know  6 it has a biological component to it.</p> <p>7 Q Okay. So the cracked layer is not -- I just  8 want to make sure I understand it -- is not oxidized  9 Prolene, we know that the cracked layer is not Prolene,  10 and we know it has a biological component to it. So  11 what is it?</p> <p>12 A I just told you what is it. It's a material  13 with a biological component to it.</p> <p>14 Q Similar to the cracks that we observed in the  15 Wood article?</p> <p>16 A They're --</p> <p>17 MR. HUTCHINSON: Object to form.</p> <p>18 THE WITNESS: They're transverse cracks.</p> <p>19 I don't know if I'd characterize them as  20 similar.</p> <p>21 Q (By Mr. Thornburgh) We saw transverse cracks  22 on the Wood article, right?</p> <p>23 A Correct, but all -- if you look at the  24 totality of all the micrographs in this matter and all</p>	<p style="text-align: center;">Page 237</p> <p>1 Q -- "depending on a number of variables  2 including the specific catalyst used."</p> <p>3 What is -- what is the differing values that  4 can influence the variability from material to  5 material?</p> <p>6 A Oh, temperature, pressure, reaction time in  7 the vessel, those can all influence molecular weight as  8 they go through the synthesis process.</p> <p>9 Q It says that, "There is a degree of  10 randomness associated with the synthesis of most  11 commercial polymers. The total number of monomeric  12 units contained within each polymer chain will vary  13 within a given sample." What does that mean?</p> <p>14 A It means that when I polymerize, when I make  15 polymers, I'm going to make polymers which are just  16 long chains of repeat units. Those individual chains  17 at the molecular level all vary in length by a little  18 bit. So I'll have chains that might be -- you know,  19 I'm going to do this arbitrarily on the table. I might  20 have chains that are this long, this long, this long  21 (indicating), and so on, and the molecular weight  22 average is the actual average of those lengths.</p> <p>23 Q Okay. So to try to control the variables  24 that happen from -- to try to control the variables in</p>

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<p>1 a molecular weight test, you'd want to use a control 2 that's as identical to the test material as possible, 3 right?</p> <p>4 A Maybe you could rephrase that one.</p> <p>5 Q Yeah, I'm just trying to understand. So I'm 6 not a scientist. So if there are variables or 7 variability between one polypropylene to another 8 polypropylene in the molecular weight, to -- if I'm 9 going to do a study, I want to try to compare the same 10 polymer as a control to the test article; is that 11 right?</p> <p>12 A If I want to look at -- are you suggesting 13 that you're trying to investigate changes in molecular 14 weight?</p> <p>15 Q Yeah.</p> <p>16 A And you need a baseline number?</p> <p>17 Q Yeah.</p> <p>18 A And the baseline would -- you would want the 19 baseline to be representative of the original material; 20 is that what you're suggesting?</p> <p>21 Q Right, yeah.</p> <p>22 A I'd say in general that makes sense.</p> <p>23 Q Okay, because you want to -- you want to -- 24 you want to reduce the variability?</p>	<p>1 pressure vessel with temperature, with time, 2 and I get a reaction to take place because I 3 catalyze it. We talk about that on page 12, 4 okay?</p> <p>5 And that building of those chains that 6 we just talked about take place in the 7 reactor, and now I convert that raw material 8 into fiber. So the baseline molecular weight 9 is largely dependent on the synthesis and 10 polymerization process that we just talked 11 about.</p> <p>12 Q (By Mr. Thornburgh) Well, one of the things 13 that can influence the polymer is the -- I think you 14 just said it -- the extrusion process --</p> <p>15 A Sure.</p> <p>16 Q -- right?</p> <p>17 A Yeah. And I'm saying there really shouldn't 18 be and wouldn't be a major difference in the extrusion 19 process between 5-0 and 6-0 that would influence the 20 molecular weight.</p> <p>21 Q But they -- you say here that -- it says 22 there is a degree of randomness associated with the 23 synthesis of most commercial polymers. The total 24 number of monomeric units contained within each polymer</p>
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<p>1 A Well, you need a reference point.</p> <p>2 Q Uh-huh.</p> <p>3 A I mean, if you're going to look at a material 4 that's aged under whatever conditions and you want to 5 know if it has degraded and you want to do that by 6 quantifying its molecular weight, you need a reference 7 sample to be able to say yes, it actually did degrade, 8 it actually did shift from some sort of baseline.</p> <p>9 Q Okay. So you want to use the same suture, 10 for example?</p> <p>11 A You certainly want to use the same material 12 that's seen the same thermal history, processing 13 history.</p> <p>14 Q So if I'm -- so, for example, if I'm going to 15 test Prolene mesh 6 mil, I want to use as my control 16 the Prolene mesh 6 mil to reduce the variability as 17 much as possible? To control, right?</p> <p>18 MR. HUTCHINSON: Object to form.</p> <p>19 THE WITNESS: Ideally, but if you use, 20 say, a 5-0 as a reference versus a 6-0, I 21 mean, the polymerization process that we've 22 talked about happens well before processing, 23 right, so this is -- this is the synthesis of 24 the material. You have raw monomer in a</p>	<p>1 chain will vary within even a given sample.</p> <p>2 A Yes, and that's why you do a molecular weight 3 analysis. You actually characterize the entire 4 distribution of the chains in your sample, and then I 5 take an average of that number. It's common practice 6 within polymers.</p> <p>7 Q And even within a given sample -- or, I'm 8 sorry, the values of commercial polypropylene will vary 9 in terms of molecular weight from 220 to 700 grams per 10 mole, and that's a pretty significant difference from 11 one commercial polypropylene to another?</p> <p>12 A Sure, but you have to remember that there are 13 literally thousands of grades of polypropylene out 14 there. Some are designed for melt spinning, some are 15 designed for injection molding, some are designed for 16 thermoforming and extrusion. All of these -- all of 17 these processes require different types and grades of 18 polypropylene to get through those manufacturing 19 processes. This is a viscosity discussion, how viscous 20 the material is in its molten state. So that's why 21 it's not uncommon to have this large spread across the 22 thousands of grades that are out there. We're talking 23 about a very specific grade Prolene with a very 24 controlled resin supply chain.</p>

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<p>1       Q So -- but as a scientist, you want to control  2       as best -- as well as you can the degree of  3       variability, right?</p> <p>4       A In a manufacturing process, I would say that  5       that's a general goal, is to minimize variability.</p> <p>6       Q Not just as a manufacturing -- manufacturer,  7       but as a scientist, you want to -- you know, you want  8       to use your -- a control that is the same as the test  9       article?</p> <p>10      A I don't want to get off --</p> <p>11      Q It seems like --</p> <p>12      A -- I don't want to get off on a tangent, but  13       in my scientific study, if I'm looking at -- trying to  14       explore a hypothesis, then I am going to vary certain  15       variables to get a response. So I think just saying  16       blanketly that I want to minimize variation in all of  17       my scientific studies, if I did that, I wouldn't have a  18       scientific study. I have to vary something to get a  19       natural response in my scientific experiment.</p> <p>20      Q But if you're not trying to explore a  21       hypothesis, but you're trying to confirm, for example,  22       the molecular weight of a given -- of an explanted  23       suture, for example, you want to compare a 5-0 suture  24       to a 5-0 control?</p>	<p>1       one filament size to the next is going to  2       shift my molecular weight statistically.</p> <p>3       Q (By Mr. Thornburgh) Well, the filament  4       size -- you just indicated that there could be a number  5       of different things that could affect the randomness  6       even within a given sample?</p> <p>7       A During synthesis, synthesis.</p> <p>8       Q Hold on a second, all right. On page 12, you  9       say, "Since there is a degree of randomness associated  10       with the synthesis of most commercial polymers, the  11       total number of monomeric units contained within each  12       polymer chain will vary from a given" -- "within even a  13       given sample."</p> <p>14      A Yes. You never get monodispersed polymer in  15       a synthesis -- in a -- in a large-scale manufacturing  16       environment that synthesizes commercial grades of  17       polymer.</p> <p>18      Q You also want to use -- well, do you know  19       what changes occurred in the manufacturing process from  20       1985 until the seven-year study was done in 1992?</p> <p>21      A You'd have to refresh my memory of the  22       document.</p> <p>23      Q Well, we know one of the things that changed  24       was they reduced the level of the Santanox, right?</p>
<p style="text-align: center;">Page 243</p> <p>1       MR. HUTCHINSON: Object to form.</p> <p>2       THE WITNESS: Ideally, but it doesn't  3       undermine any of the data that we've seen.</p> <p>4       Q (By Mr. Thornburgh) It makes the data less  5       reliable?</p> <p>6       MR. HUTCHINSON: Object to form.</p> <p>7       THE WITNESS: I disagree.</p> <p>8       Q (By Mr. Thornburgh) It increases the  9       variability?</p> <p>10      A I disagree.</p> <p>11      Q Have you looked -- have you looked at the  12       molecular weight of a 5-0 Prolene suture and compared  13       it to the molecular weight of a 4-0 Prolene suture?</p> <p>14      A I don't recall.</p> <p>15      Q Have you asked for data from Ethicon to show  16       you what the molecular weight is in a 5-0 compared to a  17       4-0?</p> <p>18      A No, I haven't asked for that.</p> <p>19      Q You'd want to look at that, right, to  20       determine whether or not there is too much variability?</p> <p>21      MR. HUTCHINSON: Same objection.</p> <p>22      THE WITNESS: Knowing what I know about  23       this resin, how it's been used, I haven't  24       seen any data that would suggest going from</p>	<p style="text-align: center;">Page 245</p> <p>1       A Correct. You asked me about the  2       manufacturing process.</p> <p>3       Q But one of the things that they did is they  4       reduced the level that they put into the Prolene resin  5       of Santanox, right?</p> <p>6       A Correct.</p> <p>7       Q That's part of the manufacturing process,  8       right?</p> <p>9       A I would have characterized that as a change  10       in the formulation, but --</p> <p>11      Q Uh-huh.</p> <p>12      A -- regardless, yes.</p> <p>13      Q Uh-huh. And do you know what other changes  14       occurred at Ethicon concerning the Prolene sutures?</p> <p>15      A You'd have to show me a document.</p> <p>16      Q Different extrusion machines, so if you go  17       from one extrusion -- or let's say a blender, you go  18       from one blender to another -- you change from a  19       blender to a different blender, that could impact  20       the -- or -- impact the variability of the molecular  21       weight, right?</p> <p>22      MR. HUTCHINSON: Object to form.</p> <p>23      THE WITNESS: No. No, because blending  24       is just going to blend the polymerized</p>

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<p>1 polymer and the additives that you're putting 2 into it into the final resin, so --</p> <p>3 MR. THORNBURGH: Well, so what other --</p> <p>4 THE WITNESS: -- I don't agree with 5 that.</p> <p>6 MR. THORNBURGH: Sorry.</p> <p>7 Q (By Mr. Thornburgh) What other changes could 8 impact the variability of the molecular weight from 9 within one sample? You say here the synthesis. What's 10 "synthesis" mean?</p> <p>11 A Synthesis is what I talked about a few 12 minutes ago. That's the conversion of small molecules 13 into one large polymer, one large molecule. That's 14 what synthesis is.</p> <p>15 Q So how do you convert it from one molecule to 16 a larger molecule?</p> <p>17 A Just like we describe in the report, you 18 initiate it with a catalyst, so you start a chemical 19 reaction, and each small molecule then reacts with its 20 neighbor until you have a large macromolecule. And 21 that's what the polypropylene is, is a large 22 macromolecule with repeat units along its structure.</p> <p>23 Q And what is the catalyst?</p> <p>24 A There's all sorts of catalysts. I think we</p>	<p>1 between the fiber diameter of a Prolene 4-0, 5-0, 6-0 2 that's going to translate into any statistical 3 difference in the molecular weight.</p> <p>4 Q Tell me what the control run of the 5-0 5 was -- well, tell me what the molecular weight control 6 run of a Prolene 5-0.</p> <p>7 A It's the same answer. I don't -- I can't 8 find one. If you have one, I'd be happy to look at it. 9 What I've seen in some of the molecular weight data 10 from the dog study, it was a 4-0 baseline material 11 that's used.</p> <p>12 Q Oh, the dog study was a 4-0 baseline?</p> <p>13 A That's what I have for data in front of me.</p> <p>14 Q And the study was -- the implanted Prolene 15 sutures were 5-0, right?</p> <p>16 A Correct.</p> <p>17 Q And you don't know what the molecular weight 18 is of the Prolene suture 5-0 in 1985?</p> <p>19 MR. HUTCHINSON: Same -- object to 20 form.</p> <p>21 Q (By Mr. Thornburgh) I mean, if you're going 22 to do a prospective study --</p> <p>23 MR. HUTCHINSON: Dan, is that question 24 withdrawn?</p>
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<p>1 mentioned a few in the report. A Ziegler or Natta 2 catalyst can be one or two of them. I'm not 3 specifically sure.</p> <p>4 Q A what or a what?</p> <p>5 A Ziegler or Natta catalyst is often used with 6 polyolefins.</p> <p>7 Q Do you know if Ethicon changed its catalysts 8 from 1985 until --</p> <p>9 A No, but all the molecular weight data tells 10 us that everything is A-okay, we're getting consistent 11 molecular weight data across the board, so nothing 12 appears to be changing.</p> <p>13 Q Well, did you -- did you -- have you -- well, 14 let me ask you this question: What is the molecular 15 weight of the control 5-0 that was ran in 1985?</p> <p>16 A I don't know if I've seen a document that 17 says what the control of the 1985 5-0 is.</p> <p>18 Q Doesn't it seem reasonable, as a scientist, 19 that if you're going to do a study that looks at 20 molecular weight and you start that study in 1985 with 21 the intention of doing molecular weight studies on 5-0, 22 that you run a control GPC of the Prolene 5-0 to see 23 what the molecular weight is in 1985?</p> <p>24 A There is not a significant enough difference</p>	<p>1 MR. THORNBURGH: Withdrawn.</p> <p>2 MR. HUTCHINSON: Okay.</p> <p>3 Q (By Mr. Thornburgh) If you're doing to a 4 prospective study --</p> <p>5 A Uh-huh.</p> <p>6 Q -- right, of these dogs and the end result 7 seven years later is to look at the molecular weight, 8 in 1985, you want to run a control of the 5-0 Prolene, 9 that's the way good science is done?</p> <p>10 A Ideally, but there's nothing wrong with using 11 a Prolene 4-0 suture here. There's nothing that tells 12 us that the molecular weight number and data we get is 13 not consistent with 5-0.</p> <p>14 Q But you don't know what the 1985 5-0 15 molecular --</p> <p>16 A It's the --</p> <p>17 MR. HUTCHINSON: Guys, I'm sorry, one at 18 a time. Dr. MacLean, you can finish your 19 answer. Mr. Thornburgh will gladly allow you 20 to do that.</p> <p>21 THE WITNESS: It's the same resin 22 formulation, it's the same base polymer, it 23 has the same molecular weight coming out of 24 the synthesis process that we've talked</p>

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<p>1       about. The differences, if any, between  2       spinning a 5-0 and 4-0 fiber are not going to  3       have a statistical influence on the molecular  4       weight. That's my opinion.</p> <p>5       Q (By Mr. Thornburgh) And you're reaching that  6       opinion without looking at the data of a 1985 control  7       5-0 Prolene, correct?</p> <p>8       A I'm reaching that opinion on being in the  9       plastics and polymer industry for 20 years, being  10       around polymers that have been synthesized, that have  11       been compounded, that have been extruded, that have  12       been manufactured. And I'm telling you, based on my  13       experience, I would not expect a difference in  14       molecular weight between a 4-0 and a 5-0 specimen.</p> <p>15       Q The better scientific thing to have done --  16       let's just throw it on the table. The better and the  17       best scientific -- the good manufacturing practice --  18       the good laboratory practice, right -- I've seen --  19       I've seen -- you've talked about good manufacturing  20       practices, you -- I think you've maybe lectured about  21       it at maybe school or somewhere, I forget, but I've  22       seen you talk about it somewhere. You're familiar with  23       good manufacturing -- or good laboratory practices,  24       GLP, right?</p>	<p>1       antioxidant?</p> <p>2       A We don't know that. You're going to cite the  3       document, I know you are, but we don't -- I don't think  4       we know, unless you can point me to a document, when  5       these reference samples were manufactured.</p> <p>6       Q Would that be important?</p> <p>7       A Not really, because the only one change that  8       we've talked about is this -- I would argue negligible  9       or slight change to the one antioxidant. That is not  10       having any bearing on the molecular weight synthesis  11       process that I've outlined for you. Those are mutually  12       exclusive. There's no interaction between those two  13       things.</p> <p>14       Q Would it change your opinion if the  15       standard -- or the average molecular weight of 1985  16       Prolene 5-0 was statistically different than the  17       molecular weight of a pristine Prolene 4-0 in 1992?</p> <p>18       A I'd need to see the data.</p> <p>19       Q Would it -- would that be important to you,  20       if there's a statistical difference?</p> <p>21       A It may, it may, but I'd need to see the data.</p> <p>22       Q Did you notice that before today?</p> <p>23       A Notice what?</p> <p>24       Q That the test suture was Prolene 5-0, but the</p>
<p style="text-align: center;">Page 251</p> <p>1       MR. HUTCHINSON: I'm sorry. Dan,  2       what --</p> <p>3       MR. THORNBURGH: Let me withdraw the  4       question.</p> <p>5       MR. HUTCHINSON: Thank you.</p> <p>6       MR. THORNBURGH: Withdraw the question.</p> <p>7       MR. HUTCHINSON: You were talking about  8       throwing something on the table, and you lost  9       me after that.</p> <p>10       MR. THORNBURGH: Let me withdraw the  11       question.</p> <p>12       THE WITNESS: Okay.</p> <p>13       Q (By Mr. Thornburgh) You understand what good  14       laboratory practices require, right?</p> <p>15       A I understand what good science requires. I  16       understand in some cases you don't have a perfect, an  17       ideal set of conditions to work with. And there is  18       nothing wrong with using a 4-0 suture as a baseline  19       here with the same exact resin formulation, same  20       manufacturing process, to establish a baseline in the  21       absence of a 5-0.</p> <p>22       Q And --</p> <p>23       A There's nothing wrong with that.</p> <p>24       Q And a change in the additives, including an</p>	<p style="text-align: center;">Page 253</p> <p>1       control in 1992 was Prolene 4-0.</p> <p>2       A Oh, sure, yes.</p> <p>3       Q Did you ask Ethicon's attorneys if they had  4       any data on the molecular weight of a 1985 Prolene 5?</p> <p>5       A No, because if you look at the data --</p> <p>6       MR. HUTCHINSON: Objection.</p> <p>7       THE WITNESS: Sorry, Chad.</p> <p>8       MR. HUTCHINSON: That's all right. I'd  9       just object to form. Counsel, I think you  10       meant 4-0, but that's fine.</p> <p>11       Q (By Mr. Thornburgh) Did you ask Ethicon's  12       attorney if they had --</p> <p>13       MR. HUTCHINSON: You can answer the  14       question.</p> <p>15       MR. THORNBURGH: Let me make sure I have  16       it right.</p> <p>17       Q (By Mr. Thornburgh) Did you ask Ethicon's  18       attorneys if they had any data on the molecular weight  19       of a 1985 Prolene 5, which was the test article, so you  20       want to look at the 1985 5-0 as the control, that would  21       be the ideal thing to do?</p> <p>22       A It would be the ideal thing to do, but when I  23       look at the data that's been compiled, it is clearly  24       obvious to me that the molecular weight is right in</p>

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<p>1 line with all the other samples and there's no  2 shifting -- there's no statistical shifting taking  3 place.</p> <p>4 Q In the 6-year-10-and-a-half month report, the  5 conclusions that were reached was that approximately 50  6 percent of the Prolene suture surface was cracked due  7 to degradation. Do you disagree with that?</p> <p>8 A Can you -- I just want to -- can you read  9 that to me one more time?</p> <p>10 Q Yeah. Conclusions on ETH.MESH.09888100.</p> <p>11 A I'm sorry --</p> <p>12 Q Exhibit --</p> <p>13 A -- I might be in the wrong exhibit.</p> <p>14 Q I'm sorry. Exhibit --</p> <p>15 A Sixteen?</p> <p>16 Q -- 16.</p> <p>17 A Okay. And the Bates number one more time.</p> <p>18 MR. HUTCHINSON: One hundred.</p> <p>19 THE WITNESS: One hundred?</p> <p>20 MR. THORNBURGH: Yep.</p> <p>21 THE WITNESS: Got it. Okay.</p> <p>22 Q (By Mr. Thornburgh) You see the conclusions  there?</p> <p>23 A I do.</p>	<p>1 almost all the other researchers have made. They have  2 equated the appearance of cracking to degradation. And  3 it's fundamentally flawed.</p> <p>4 MR. THORNBURGH: Change the tape.</p> <p>5 THE VIDEOGRAPHER: We are now going off  6 the video record. The time is currently  7 4:26 p.m. This is the end of Tape No. 4.</p> <p>8 (Recess taken.)</p> <p>9 THE VIDEOGRAPHER: We are now back on  10 the video record with Tape No. 5. The time  11 is currently 4:42 p.m.</p> <p>12 Q (By Mr. Thornburgh) Doctor, before we went  13 off the record, we were talking about the  14 6-year-10-month -- 10.5 month study, and we were then  15 going to talk about the seven-year data on the Prolene  16 study.</p> <p>17 MR. THORNBURGH: Go ahead and mark this  18 Exhibit No. 17.</p> <p>19 (Exhibit 17 marked for identification.)</p> <p>20 Q (By Mr. Thornburgh) This is the October  21 15th -- it's the October 15th, 1992 seven-year data for  22 the 10-year dog study. See the "IR and IR Microscopy"  23 section?</p> <p>24 A I do.</p>
<p style="text-align: center;">Page 255</p> <p>1 Q The only explanted suture still undamaged  2 after 6 years and 10-and-a-half months in vivo is the  3 5-0 PVDF suture, right?</p> <p>4 A That's what it says.</p> <p>5 Q Approximately 50 percent of the Prolene  6 surface was cracked due to degradation; do you disagree  7 with that?</p> <p>8 A If you interpret Prolene suture surface as  9 being the actual Prolene material, I absolutely  10 disagree with that. I don't -- I don't -- I don't  11 disagree that there was probably a 50 percent  12 calculation or estimation made, but I disagree that the  13 cracking was taking place in the Prolene.</p> <p>14 Q You disagree that it was degraded, right?</p> <p>15 A Oh, without a doubt. The data tells us that.</p> <p>16 Q Okay. So this is another scientist,  17 Dr. Lindemann, that you disagree with --</p> <p>18 A What page you are you on?</p> <p>19 Q -- who -- 102, is the person who signed the  report.</p> <p>21 MR. HUTCHINSON: Object to form.</p> <p>22 Q (By Mr. Thornburgh) You disagree with  Ethicon's internal scientist, Dr. Lindemann?</p> <p>24 A Correct. He's made the same mistake that</p>	<p style="text-align: center;">Page 257</p> <p>1 Q So they performed some chemical analysis,  2 right?</p> <p>3 A They did.</p> <p>4 Q Using infrared?</p> <p>5 A They do.</p> <p>6 Q And they did -- they analyzed the Prolene  7 sutures that were explanted, correct?</p> <p>8 A Correct.</p> <p>9 Q This is the first time they actually did the  IR analysis, right?</p> <p>11 A Correct. I believe you're correct.</p> <p>12 Q And on October 15th, 1992, in this report the  authors conclude that, "The IR microspectroscopy was  used to examine cracked areas of Ethilon, Novafil, and  Prolene explants. IR spectra obtained for cracked  Prolene specimen (Figure A) showed possible evidence of  slight oxidation." Did I read that accurately?</p> <p>18 A Yes. "Possible evidence of slight  oxidation," that's what it says.</p> <p>20 Q Do you disagree that they found possible  evidence of slight oxidation?</p> <p>22 A I do.</p> <p>23 Q Okay. And I assume that you believe that  they were seeing protein?</p>

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<p>1       A    Correct. Well, it's either protein and/or 2    those aliphatic ester compounds that we talked about 3    earlier.</p> <p>4       Q    The ester compounds?</p> <p>5       A    Correct.</p> <p>6       Q    And is that what -- is that what you're 7    opining is the -- what causes plasticization?</p> <p>8       A    Correct.</p> <p>9       Q    And why is that your opinion?</p> <p>10      A    Well, because you have to look at the 11     totality of the data. So let's look at a couple of 12     things to kind of show that. This is what --</p> <p>13      Q    So for the record, you're referencing 14     Exhibit 2 of your expert report -- or, no, you have 15     attachments to your expert report, which include some 16     dog photos, right?</p> <p>17      A    Correct.</p> <p>18      Q    Those aren't actually in your report that you 19     submitted?</p> <p>20      A    Correct. These are just additional 21     documents. This one ends in 0674, depo -- it's 22     ETHICON.MESH.0006474.</p> <p>23      Q    Okay. And that's dog -- that's seven-year 24     dog explant from what dog?</p>	<p>1       Q    And this is in Exhibit 2, right?</p> <p>2       A    It is in Exhibit 2, correct.</p> <p>3       Q    Okay. And the Prolene control is what?</p> <p>4       A    It's -- you'd have to look at the data on a 5     separate page. Let's just stick with me for one 6     second. So about two-thirds of the way down on the 7     table that's on the ETHICON.MESH document that I just 8     read, you'll actually see a series of data points for 9     Prolene.</p> <p>10      And there's one particular line, "Prolene, 11     Dog 2008, Site 2," so that is the exact dog and site 12     location that's represented by the image that we just 13     spoke about on Ethicon document ending in 6474. And if 14     you look at the tensile elongation data with that 15     particular type of fiber, I have achieved 70.76 percent 16     elongation at break.</p> <p>17      Q    Okay. And they're comparing -- to get the 18     elongation changes, they compared the Prolene --</p> <p>19      A    Well, this is not a -- let's be careful. 20      This is not a change. This is the actual number, the 21     amount the material stretched before it actually broke 22     in the tensile test.</p> <p>23      Q    Okay, but you have to compare that to a 24     control, right?</p>
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<p>1       A    This is from Dog 2008. This is Site 2.</p> <p>2       Q    Okay. And why is it your opinion that -- 3     what's your opinion? What are you trying to show us?</p> <p>4       A    Okay. So in this -- in this micrograph, 5     I'm actually showing you a stretch of a fiber from 6     Site No. 2, and it has this -- what people have coined 7     or termed "severe degradation." You've got a number of 8     different concentric transverse cracks that are 9     happening in parallel along the length of the suture, 10    and everyone looks at this specimen, finds the carbonyl 11    functionality, and says it's oxidized.</p> <p>12      And then not only do they say it's oxidized, 13    they say this is signs of embrittlement. So -- but 14    when you look at the actual data, and we actually have 15    tensile data for Dog 2008, Site 2, if you look at the 16    tensile properties, there is no embrittlement taking 17    place. As a matter of fact, you see an increase of 18    roughly a hundred percent increase in ductility.</p> <p>19      Q    Tell us where the tensile data is that you're 20     referencing.</p> <p>21      A    Sure. I'm on ETHICON.MESH.11336182.</p> <p>22      Q    Okay. And this is tensile testing that was 23     done at seven years?</p> <p>24      A    That's correct.</p>	<p>1       A    We do, and we do that.</p> <p>2       Q    What's the control?</p> <p>3       A    The control data, off the top of my head, is 4     approximately 37 percent. I'll get you the exact 5     number. So reading off of my chart in my larger expert 6     report, on page 45, I'm in Figure 8, top right-hand 7     corner. Elongation at break for Prolene at times zero, 8     the control, is approximately 37 percent off of the 9     graph.</p> <p>10      So as we have survived seven years in vivo, 11    we have actually doubled the amount of ductility and 12    the amount the material can stretch despite the fact 13    that we see a carbonyl peak and despite the fact that 14    we see what some people say a large amount of cracking 15    is on the surface of the fiber.</p> <p>16      In addition to that, if you want to talk 17     about true degradation, you look at the molecular 18     weight data for seven years, and we see no change. 19     There is no difference, no statistical difference in 20     the molecular weight values for a seven-year dog study 21     compared to what the times zero molecular weight was.</p> <p>22      So between no molecular weight, the doubling 23     of elongation, and despite the fact that we see 24     cracking in the carbonyl peak, it's clear that the</p>

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<p>1 material is not degrading. Your experts are claiming  2 that if I've got degradation, I must have  3 embrittlement, and we are seeing the exact opposite.  4 We do not see embrittlement. We see a shift in the  5 exact opposite direction. You can't have that both  6 ways.</p> <p>7 Q So you would see a reduction in the tensile  8 strength, right?</p> <p>9 A In the elongation. Plasticization in  10 polymers, you're going to have two things that are  11 definitely going to happen. You're going to have an  12 increase in ductility, which we just stepped through.  13 We're going to have a slight reduction in modulus  14 because you're getting more flexible, the material is  15 actually becoming more compliant. And the seven-year  16 dog study tells us that the -- you know, the average  17 breaking strength is really unaffected over the  18 seven-year period.</p> <p>19 So -- and if you look at the bulk physical  20 properties that are important to this mesh in terms of  21 being pliable, ductile, and maintaining its strength,  22 they're all there. And at the end of the day, this  23 coating material, in terms of truly identifying what it  24 is, is an academic exercise. It's an academic exercise</p>	<p>1 MR. THORNBURGH: Let's go off the record  2 for a minute.</p> <p>3 THE VIDEOGRAPHER: We are now going off  4 the video record. The time is currently  5 4:51 p.m.</p> <p>6 (Off the record.)</p> <p>7 THE VIDEOGRAPHER: We are now back on  8 the video record. The time is currently  9 4:56 p.m.</p> <p>10 Q (By Mr. Thornburgh) Okay, before we went off  11 the record, you were -- you had said that one of the  12 reasons why you believe that the Prolene did not  13 degrade as a result of oxidation was because there was  14 10-year data collected at the seven-year period of both  15 tensile strength and molecular weight.</p> <p>16 A And elongation and modulus, correct.</p> <p>17 Q Okay. And you had -- and what page are you  18 looking at?</p> <p>19 A I'm looking at the -- I'll call it the raw  20 data from the 10-year dog study. It ends with  21 ETHICON.MESH.11336084.</p> <p>22 Q Okay. And so the date of the memo is  23 August 18th, 1988, right?</p> <p>24 A It is.</p>
<p style="text-align: center;">Page 263</p> <p>1 because it does not matter. Whatever it is, even  2 though it has a carbonyl functional group perhaps  3 associated with it, it does not matter.</p> <p>4 Q Okay. Let me -- let's go back and talk about  5 all those issues.</p> <p>6 A Sure.</p> <p>7 Q Okay?</p> <p>8 A Sure.</p> <p>9 Q Number one, where's your data? What data are  10 you relying on for your chart concerning the control  11 tensile strength for Prolene 5-0? Where is that data  12 at?</p> <p>13 A It's the same discussion we had. So the data  14 has been -- the data has been either normalized or the  15 4-0 tensile strength has been used.</p> <p>16 Q So they used -- so, again, the test model or  17 the test -- they tested in this dog study a 5-0 suture  18 in 1985 and they compared the tensile strength in 1992  19 to a 4-0 suture, correct?</p> <p>20 A They certainly did that in the molecular  21 weight. I just don't recall off the top of my head if  22 they did that for the tensile strength.</p> <p>23 Q Well, let's look real quick.</p> <p>24 A Sure.</p>	<p style="text-align: center;">Page 265</p> <p>1 Q And the title of this document is "Ten-Year  2 Prolene BSR Study," right?</p> <p>3 A Correct.</p> <p>4 Q And what we know about the tensile strength  5 here is that they only looked at Year 1 and 2?</p> <p>6 A In this data set, correct.</p> <p>7 Q Okay. And in Year 1 and 2, we know from  8 looking at the two-year dog study there wasn't any  9 evidence at the two-year interval of degradation even  10 in the Prolene suture, correct?</p> <p>11 A Rephrase that question.</p> <p>12 Q We know from looking at the studies that  13 there was no evidence of degradation in the two-year  14 period of the 10-year dog study, correct?</p> <p>15 A Based on what? How do we know that?</p> <p>16 Q We looked at the dog study and we looked at  17 the five-year dog study that said Prolene is now  18 degraded compared to the two-year mark when there was  19 no degradation.</p> <p>20 A Oh, you're referencing that text.</p> <p>21 Q Yes. Do you remember that?</p> <p>22 A I do, sure.</p> <p>23 Q Okay. So there was no evidence of surface  24 cracking on the sutures at two years, right?</p>

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<p>1 A Correct.</p> <p>2 Q And there was no conclusion that those -- at</p> <p>3 the two-year period that there was any degradation,</p> <p>4 right?</p> <p>5 A Correct.</p> <p>6 Q So then they issued a 10-year Prolene BSR</p> <p>7 study in 1988 showing only data up to two years,</p> <p>8 correct?</p> <p>9 A In that memo, correct.</p> <p>10 Q Okay. So where's the other memo that you're</p> <p>11 referencing?</p> <p>12 A It's on ETH.MESH.11336182.</p> <p>13 Q Okay. And this is dated October 19th, 1992?</p> <p>14 A Correct.</p> <p>15 Q And it says, "Attached table shows the</p> <p>16 physical properties of explanted and baseline samples</p> <p>17 of size 5-0 Ethilon, Novafil, Prolene, and PVDF sutures</p> <p>18 at the seven-year mark of the 10-year BSR study,"</p> <p>19 right?</p> <p>20 A Correct.</p> <p>21 Q It says the tensile -- if you could look down</p> <p>22 at the bottom paragraph, "Seven-year testing conditions</p> <p>23 were based on the one-year and two-year data to keep</p> <p>24 them consistent throughout the study. Tensile testing</p>	<p>1 more than taking the suture, placing it in an</p> <p>2 instrument that allows me to pull it in tension, and I</p> <p>3 measure how stiff that fiber is, how much stretching it</p> <p>4 undergoes before it fractures and breaks, and what the</p> <p>5 ultimate strength of that fiber is as it breaks. And</p> <p>6 all they're saying is that for consistency purposes,</p> <p>7 they kept the one-, the two-, and the seven-year</p> <p>8 conditions the same, which is what I would expect them</p> <p>9 to do.</p> <p>10 Q If you turn the page -- so let me ask you</p> <p>11 this: At the seven-year mark, did they use the 5-0</p> <p>12 Prolene suture as their control?</p> <p>13 A It's whatever the control is in the previous</p> <p>14 Ethicon document that we talked about a few minutes</p> <p>15 ago. It's the -- there are data points that say</p> <p>16 unimplanted fibers for each material type, and that's</p> <p>17 the control.</p> <p>18 Q And so they did that for the tensile testing,</p> <p>19 but not for the GPC?</p> <p>20 A It appears so. It appears so.</p> <p>21 Q If you turn to ETH.MESH.11336182, which was</p> <p>22 the back side of the 10-year Prolene BSR study --</p> <p>23 A Give me the last three again.</p> <p>24 Q Yeah, it's -- well, on mine, it's 182.</p>
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<p>1 conditions were 1 in." -- what's that, inch per</p> <p>2 minute --</p> <p>3 A Inch per minute, correct.</p> <p>4 Q -- "crosshead speed for the Prolene samples,</p> <p>5 and 5 inch per minute for all other samples with gauge</p> <p>6 strength (GL) of 1 inch," right?</p> <p>7 A Correct.</p> <p>8 Q So they used the data from the one- and</p> <p>9 two-year data to keep it consistent throughout the</p> <p>10 study. Did you understand what that means?</p> <p>11 A I do. They just -- they made some</p> <p>12 consistency on the test parameters in terms of the rate</p> <p>13 at which you pull the fiber in tension between one,</p> <p>14 two, and seven years, and that's what I would expect</p> <p>15 them to do.</p> <p>16 Q So the seven-year testing conditions were</p> <p>17 based on the one- and two-year data to keep them</p> <p>18 consistent throughout the study. I don't understand</p> <p>19 what that means. So if you can try to --</p> <p>20 A Sure.</p> <p>21 Q -- explain it to me again.</p> <p>22 A Yeah. So what they mean, the testing</p> <p>23 conditions are essentially the rate at which I pull the</p> <p>24 fiber to get my tensile properties. This is nothing</p>	<p>1 A One eight two.</p> <p>2 MR. HUTCHINSON: Of which exhibit?</p> <p>3 MR. THORNBURGH: In his -- in his</p> <p>4 Exhibit No. 4 [sic]. Sorry.</p> <p>5 THE WITNESS: I'm on 182.</p> <p>6 Q (By Mr. Thornburgh) Okay. So it's where you</p> <p>7 just were on the 10-year Prolene BSR study. You were</p> <p>8 just there a moment ago.</p> <p>9 A Okay.</p> <p>10 Q So go back to where you were when we were</p> <p>11 looking at the --</p> <p>12 A The raw data?</p> <p>13 Q Yep.</p> <p>14 A Memo, August 18th, 1988?</p> <p>15 Q Yeah.</p> <p>16 A Dr. Moy?</p> <p>17 Q Yep.</p> <p>18 A Okay.</p> <p>19 Q All right. Turn the page to the second page</p> <p>20 of the memo with the raw data.</p> <p>21 A Now -- hold on a second. Now you're on the</p> <p>22 seven-year data. Is that what that says?</p> <p>23 Q Yes, it's the seven -- because the 10-year</p> <p>24 data doesn't exist.</p>

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<p>1        A No, no, that's not what I'm asking. When I  2 turn the page that we were just on, I get a different  3 document, so I'm trying to make sure we're working from  4 the same document. That's all.</p> <p>5        Q This is from Mark Cofone dated October 19th,  6 1992.</p> <p>7        A I thought we were just on the August 18th,  8 1988 document.</p> <p>9        Q No. That was -- that was -- previously we  10 were.</p> <p>11      A Okay.</p> <p>12      Q So let me --</p> <p>13      MR. HUTCHINSON: Dan, if you have a copy  14 of the document to give him, I think that  15 would help us --</p> <p>16      MR. THORNBURGH: Here we go.</p> <p>17      MR. HUTCHINSON: -- so we're all on the  18 same page.</p> <p>19      MR. THORNBURGH: Just mark this as  20 Exhibit No. 18.</p> <p>21      (Exhibit 18 marked for identification.)</p> <p>22      (Discussion off the written record.)</p> <p>23      Q (By Mr. Thornburgh) Here you go. Exhibit  24 No. 18 is in front of you. We're looking at the data</p>	<p>1        That difference is not -- that difference,  2 even though there is one between the two rates, within  3 the Prolene itself, they maintain the same rate. So we  4 aren't getting a different response from the Prolene  5 because we've -- we haven't changed its test  6 conditions.</p> <p>7        Q Well, we have changed the test conditions  8 because we're comparing it to the one- and two-year  9 data, right?</p> <p>10      A Yeah, but if you look at the one and two -- I  11 think we just read that they've kept that applied  12 crosshead speed the same based on the type of fiber  13 material that they've used. So Prolene, they maintain  14 the 1-inch-per-minute testing conditions,  15 tensile-testing conditions were 1 inch per minute  16 crosshead speed for the Prolene samples. We just read  17 that same type of text as a footnote on the one- and  18 two-year data. So they're just trying to be consistent  19 amongst the materials that they've -- that they've  20 tested.</p> <p>21      Q So they do 1-inch-per-minute crosshead speed.  22 What's the difference between crosshead speed and chart  23 speed?</p> <p>24      A Chart speed is actually -- these are old</p>
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<p>1        from the seven-year BSR analysis, right?</p> <p>2        A Yes, correct.</p> <p>3        Q And so if you look at -- if you look right  4 here, for all of the other sutures, the tensile testing  5 conditions were 1 inch per minute crosshead speed, but  6 for Prolene it was switched to -- the Prolene samples,  7 it was changed to 5 inches per minute for all -- sorry,  8 hold on a second. So for Prolene, the testing  9 conditions were 1 inch per minute crosshead speed for  10 Prolene.</p> <p>11      A Correct.</p> <p>12      Q For all other samples, it was 5 inches per  13 minute for all -- for the rest of the samples. Why is  14 that? Why would they change the protocol for Prolene  15 compared to the other sutures that were tested?</p> <p>16      A I don't know why that choice was made. When  17 I read this paragraph, it tells me that the original --  18 what I'll call time zero or control or unimplanted  19 specimens, when they were tensile tested, the Prolene  20 was tested at 1 inch per minute and the other samples  21 were tested at the 5-inch-per-minute rate. I think  22 they recognized that difference, and just to be  23 consistent throughout the entire study, they stuck with  24 those differences.</p>	<p>1        instruments. Chart speed is actually you're plotting  2 with an ink charter the data points you're collecting  3 from the mechanical test. So every -- whatever that  4 rate is is how often you're actually putting a dot or a  5 piece of -- a drop of ink on your chart that actually  6 charts this data. So it's just -- it's a very old  7 piece of equipment. They don't use those charts these  8 days. But they're unrelated, and chart speed has no  9 bearing whatsoever on the material properties.</p> <p>10      Q All right. But if you look at the  11 August 18th, 1988 BSR study --</p> <p>12      A Uh-huh.</p> <p>13      Q -- okay -- are you looking at it?</p> <p>14      A I am.</p> <p>15      Q Okay. It says the conditions used for data  16 analysis were 1 inch per minute crosshead speed (XH)  17 and 10 inches per minute chart speed for the one-year  18 Prolene controls and explants, 1 inch per minute XH and  19 5 minute [sic] per minute CS for the two-year Prolene  20 samples, and 5 inches per minute and 20 inches per  21 minute for all other samples.</p> <p>22      A Correct. So let's break that down.</p> <p>23      Q Why are they changing it -- why are they  24 doing it two different -- I'm trying to understand why</p>

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<p>1    they're doing one-year different than the two-year and  2    the two-year --</p> <p>3    A    They're not. If you really parse these  4    paragraphs out, the one consistent factor that's talked  5    about here is the rate that's being applied for  6    Prolene. It's 1 inch per minute crosshead speed at one  7    year, it's 1 inch per minute crosshead speed at two  8    years for Prolene, and it's 1 inch per minute crosshead  9    speed at seven years for Prolene. So they have  10   maintained consistency in the rate at which they pull  11   that specimen for all the Prolene samples.</p> <p>12   Q    Did they report the chart speed at the  13   seven-year period?</p> <p>14   A    They didn't, but I just told you that the  15   chart speed is irrelevant. It has nothing to do with  16   the mechanical properties. It's just a matter of the  17   chart that gets produced from the data.</p> <p>18   Q    Okay. And GPC --</p> <p>19   A    Okay.</p> <p>20   Q    -- again, for GPC, which was a -- is a bulk  21   analysis to analyze the molecular weight, right?</p> <p>22   A    Correct.</p> <p>23   Q    And if we're looking at the same exhibit, 18,  24   on page ending in 218 -- are you there?</p>	<p>1    parse the data, the control molecular weight is --  2    let's look at weight average for a second. It's  3    324,000 units. And the two Prolenes from Site 1 and  4    Site 6 are 322 and 323. So there's no meaningful  5    difference between those numbers. You're talking  6    hundreds of thousands of molecular weight units and  7    you're talking in the -- on the order of 1 percent of  8    that is changing between those numbers. There's just  9    no statistical difference between those data. The fact  10   that it goes from 324 to 323 to 322 is probably why she  11   tried -- he or she tried to be safe with this  12   explanation and say "significant," but there's no  13   difference in that data.</p> <p>14   Q    It's a -- it's a bulk analysis, though,  15   right?</p> <p>16   A    It is a -- it is a bulk analysis.</p> <p>17   Q    And a bulk analysis looks at the entire --  18   the bulk of the entire sample when it does -- when it  19   analyzes the molecular weight?</p> <p>20   MR. HUTCHINSON: Object to form.</p> <p>21   THE WITNESS: It analyzes the bulk of  22   the material, correct.</p> <p>23   Q    (By Mr. Thornburgh) Okay. And so if  24   Dr. Barbolt is correct that the Prolene only undergoes</p>
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<p>1    A    Two one eight. Am I supposed to be in  2    Exhibit 18 or am I on --</p> <p>3    Q    Yeah, 18 --</p> <p>4    A    Okay.</p> <p>5    Q    -- since we're using it.</p> <p>6    A    Okay. Okay.</p> <p>7    Q    Okay. Again, so the -- obviously the control  8    is different than the test article, right?</p> <p>9    A    It's a different size suture, same material.</p> <p>10   Q    And if you look at the conclusions and  11   comments, "Comparison of seven-year explants to current  12   4-0 Prolene sutures indicates no significant  13   degradation," right, that's the conclusion?</p> <p>14   A    That's correct.</p> <p>15   Q    Not saying there isn't degradation, they're  16   saying there isn't significant degradation?</p> <p>17   A    They've used the word "significant  18   degradation" because they're trying to be very  19   scientifically astute here. These molecular weight  20   numbers have -- we've talked about these -- they have  21   ranges to them, and they're just saying that within  22   statistical -- within statistical bounds of the data,  23   that they're all about the same.</p> <p>24   As a matter of fact, I mean, if you really</p>	<p>1    surface degradation on the outer core or the outer  2    skin, the bulk analysis would not be able to identify a  3    change in molecular weight --</p> <p>4    A    No.</p> <p>5    Q    -- a significant change in molecular weight?</p> <p>6    A    That's incorrect. We've done that analysis.  7    That's in my report. We've used a rule of mixtures.  8    We've used Jordi's data to characterize the degraded --  9    the alleged degraded molecular weight. And based on  10   our work, based on our analysis, the bulk material  11   analysis would actually catch any shifts that are  12   happening out in the fiber.</p> <p>13   Q    You assume that the --</p> <p>14   MR. HUTCHINSON: I'm sorry.</p> <p>15   MR. THORNBURGH: I'm sorry.</p> <p>16   MR. HUTCHINSON: No, I'm sorry.</p> <p>17   Dr. MacLean, were you finished?</p> <p>18   THE WITNESS: I'm finished.</p> <p>19   Q    (By Mr. Thornburgh) The assumption that you  20   made to reach that conclusion was a molecular -- a  21   depth of 4 microns in the degraded surface, right?</p> <p>22   A    Correct.</p> <p>23   Q    Why did you make that assumption?</p> <p>24   A    Because it's kind of the running number that</p>

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<p>1 your experts keep using, including Dr. Iakovlev.</p> <p>2 Q What page of your report are you looking at?</p> <p>3 A Fifty-five.</p> <p>4 Q Did you go -- did you measure any cracked</p> <p>5 depths in any of the analysis done by Dr. Jordi?</p> <p>6 A I don't recall whose measurements I've looked</p> <p>7 at. I know I've seen plenty of micrographs with scales</p> <p>8 on them that you can take either a direct measurement</p> <p>9 yourself or do a rough estimation based on the scale</p> <p>10 bar.</p> <p>11 Q So you took the molecular weight data from</p> <p>12 Dr. Jordi --</p> <p>13 A Correct.</p> <p>14 Q -- and assumed a surface degradation that is</p> <p>15 as -- that goes as deep as 4 microns?</p> <p>16 A Correct. That's what this analysis is.</p> <p>17 Q If the micron -- if the average micron depth</p> <p>18 was 2 microns, how would that change your analysis?</p> <p>19 A You'd have to rerun the calculation. You're</p> <p>20 going to get probably closer to the bulk number than</p> <p>21 you are with the 51,000 number that we have at 4</p> <p>22 microns.</p> <p>23 Q So if you assume 4 microns, it gets you</p> <p>24 outside of the standard deviation for the molecular</p>	<p>1 Counsel?</p> <p>2 Q (By Mr. Thornburgh) Do you understand that?</p> <p>3 A If you look at what we did, he talks about a</p> <p>4 specific melt temperature associated with the fiber.</p> <p>5 And then if you go to the literature and you assume</p> <p>6 degradation, the corresponding molecular weight assumed</p> <p>7 with his -- sorry, associated with his suppressed melt</p> <p>8 temperature is the number that we used. So we used his</p> <p>9 information from Bellew to get at the molecular weight</p> <p>10 of what a degraded crust would be, and we coupled that</p> <p>11 with, I would say, nominal crust thicknesses that we've</p> <p>12 seen in the micrographs.</p> <p>13 Q You're going to have to walk me through that</p> <p>14 because --</p> <p>15 A Okay.</p> <p>16 Q -- that was one -- that was one sample in the</p> <p>17 Bellew case, right?</p> <p>18 A It was one sample, but he put it in his</p> <p>19 report.</p> <p>20 Q But it's one -- so you looked at one sample,</p> <p>21 you assumed that it was a 4 --</p> <p>22 A I didn't look at one --</p> <p>23 MR. HUTCHINSON: Hey, guys.</p> <p>24 MR. THORNBURGH: Let me just finish the</p>
<p style="text-align: center;">Page 279</p> <p>1 weight?</p> <p>2 A At 4 microns, it does, correct.</p> <p>3 Q At 2 microns, it gets you closer to the bulk</p> <p>4 analysis, which would wash out the molecular weight</p> <p>5 changes on the surface, they'd be masked by the bulk?</p> <p>6 A It could. Yeah, at some smaller crust</p> <p>7 thickness, you would be within the statistical confines</p> <p>8 of the original data.</p> <p>9 Q And you took no measurements of Dr. Jordi's</p> <p>10 micron crack depth -- his crack depth -- strike that.</p> <p>11 You took no measurements of Dr. Jordi's</p> <p>12 samples to determine the crack depths of the explants</p> <p>13 that were actually included in the GPC analysis?</p> <p>14 MR. HUTCHINSON: Object to form.</p> <p>15 Counsel, are you asking if he looked at</p> <p>16 Dr. Jordi's samples?</p> <p>17 Q (By Mr. Thornburgh) Did you -- you didn't go</p> <p>18 back and -- you didn't look -- did you look at</p> <p>19 Dr. Jordi's deposition and see what --</p> <p>20 A I looked at his Bellew report. He had scores</p> <p>21 of micrographs of cracked -- surface cracked fibers.</p> <p>22 Q Well, the GPC data came from the Lewis</p> <p>23 report.</p> <p>24 MR. HUTCHINSON: Is that a question,</p>	<p style="text-align: center;">Page 281</p> <p>1 question.</p> <p>2 THE WITNESS: Sure.</p> <p>3 Q (By Mr. Thornburgh) You looked at -- you</p> <p>4 looked at a sample, the Bellew sample, and assumed that</p> <p>5 it had a crack depth of 4 microns, right?</p> <p>6 A Correct.</p> <p>7 Q One sample based on -- based on your analysis</p> <p>8 of the SEM images or what?</p> <p>9 A You're mischaracterizing what Dr. Jordi did.</p> <p>10 If you read what I wrote in my report, it says the</p> <p>11 conclusion drawn from this is incorrect. Dr. Jordi</p> <p>12 reported an average melting temperature of the Bellew</p> <p>13 explanted samples, plural, of 124 degrees C compared to</p> <p>14 126 degrees C.</p> <p>15 Q You're reading on page 54, right?</p> <p>16 A Correct.</p> <p>17 Q And so you say, "According to Dr. Jordi, the</p> <p>18 over 50 degree Celsius decrease in observed melting</p> <p>19 temperature can be considered proof of sample</p> <p>20 oxidation."</p> <p>21 Okay, so how do you go from 50 degrees</p> <p>22 Celsius decrease in observed melting temperature to</p> <p>23 assuming or making an assumption that the crack depth</p> <p>24 is 4 microns? Is that --</p>

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<p>1       A I don't. I don't. They're mutually  2       exclusive. So I take his suppressed melt temperature  3       from multiple measurements, not one, and that's 124  4       degrees centigrade. Then you go out to the literature  5       and you find a relationship, a meaningful relationship  6       between melt temperature and molecular weight. And the  7       molecular weight that would correspond to 124 degrees  8       melt temperature is 4500 units, molecular weight units.  9       So that's done separate. We have now quantified this  10      hypothetical degraded crust molecular weight.</p> <p>11       The second part of that analysis is now to do  12       the calculation, to do the rule of mixtures on page 55.  13       You need to -- you need to choose a crust thickness to  14       do the calculation, and we chose the crust thickness  15       based on the thicknesses that were either observed in  16       the micrographs or taken from some of the experts, you  17       know, Dr. Iakovlev's report, things like that.</p> <p>18       Q The 124-degree change that you're referring  19       to in Bellew, are you talking about the thermo -- the  20       thermal analysis that he did on the Bellew explant?</p> <p>21       A I am.</p> <p>22       Q Okay. So he took one measurement of one  23       explant that was treated in sodium hypochlorite, had  24       a -- what showed a decrease in its melt point at 124,</p>	<p>1       A Correct. And I was mistaken. I should have  2       looked at my footnotes. That estimation -- I wouldn't  3       call it an assumption -- comes from Dr. Iakovlev's  4       report in the consolidated case, as well as an Ethicon  5       document, ETH.MESH.12831405 and 1406.</p> <p>6       Q Okay. So it came from Dr. Iakovlev's report  7       of several different TVT explants?</p> <p>8       A Correct. We took an average.</p> <p>9       Q Okay. You took an average of how many?</p> <p>10      A Well, whatever his data was. I think he  11       shows data from anywhere from less than a micron or  12       about a micron all the way up to 7 plus microns, and we  13       chose 4 as a nominal average.</p> <p>14       Q How many years of implantation?</p> <p>15      A You'd have to defer to his data. I think it  16       was several years. Seven years, maybe, whatever his  17       data is. We can pull it up.</p> <p>18       Q So you don't have -- you don't have the data  19       in here to tell me how many explants were analyzed to  20       reach an assumption that the surface degradation depth  21       would be 4 microns?</p> <p>22      A It's --</p> <p>23      MR. HUTCHINSON: Object to form.</p> <p>24      MR. THORNBURGH: Go ahead.</p>
<p style="text-align: center;">Page 283</p> <p>1       and then so you used that one data point --</p> <p>2       A It's not one data point.</p> <p>3       Q Do you have -- do you have Dr. Jordi's expert  4       report with you?</p> <p>5       A I don't think I do.</p> <p>6       Q Do you have it in this -- right here  7       (indicating)?</p> <p>8       A No, I don't.</p> <p>9       Q I think I have it. Hold on one second.</p> <p>10      MR. THORNBURGH: Let's go off the  11       record. I just want to understand your  12       opinion.</p> <p>13      THE VIDEOGRAPHER: We're now going off  14       the video record. The time is currently  15       5:22 p.m.</p> <p>16      (Off the record.)</p> <p>17      THE VIDEOGRAPHER: We are now back on  18       the video record. The time is currently  19       5:29 p.m.</p> <p>20      Q (By Mr. Thornburgh) Okay. So in your  21       report, you state that the -- you assume that the crack  22       depth is 4 microns, and you testified that that  23       assumption was based on your review of the Bellew nano  24       thermal analysis; is that correct?</p>	<p style="text-align: center;">Page 285</p> <p>1       THE WITNESS: It's not an assumption.  2       It's based on your expert's data. It's a  3       nominal average of your expert's data.</p> <p>4       Q (By Mr. Thornburgh) Hold on a second. Let  5       me ask a couple questions --</p> <p>6       A Okay.</p> <p>7       Q -- because you understand that Dr. Iakovlev  8       opines that the longer the mesh is implanted in the  9       body, the greater the depth of the bark or the degraded  10       core, right?</p> <p>11      A Correct.</p> <p>12      Q Okay. So you then used Iakovlev's --  13       Dr. Iakovlev's data and also looked at Dr. Jordi's  14       thermal analysis, or how did you --</p> <p>15      A It was nano thermal analysis data.</p> <p>16      Q And then based on both the cracked depths of  17       Dr. Iakovlev's report --</p> <p>18      A And Ethicon's, correct.</p> <p>19      Q -- and Ethicon's report and Dr. Jordi's nano  20       thermal analysis, you somehow reach a conclusion that  21       the crack depth would be 4 microns, which would --  22       which would mean that a GPC study would not hide the  23       degradation and molecular weight loss on the -- on the  24       surface area. Is that --</p>

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<p>1           MR. HUTCHINSON: Object --</p> <p>2           Q -- am I understanding it correctly?</p> <p>3           MR. HUTCHINSON: Object to form.</p> <p>4           THE WITNESS: I'm just going to -- I'm</p> <p>5           just going to try to explain what I did one</p> <p>6           more time, and then maybe you can ask me a</p> <p>7           follow-up question.</p> <p>8           We used Dr. Jordi's thermal analysis</p> <p>9           data to convert to an alleged degraded -- or</p> <p>10          a hypothetical degraded polypropylene of 4500</p> <p>11          atomic units. We took nominal crust</p> <p>12          thicknesses from your expert's report and</p> <p>13          some Ethicon documents that are footnoted on</p> <p>14          page 55, and we ran the calculation. And</p> <p>15          when you use those data points, you get a</p> <p>16          statistically different molecular weight.</p> <p>17          You don't get something that would be</p> <p>18          so-called washed out.</p> <p>19          Q (By Mr. Thornburgh) But is that analysis</p> <p>20          using the calculation that you would get from GPC?</p> <p>21          A It's comparing it to the actual GPC data. So</p> <p>22          the -- we're making this comparison based on actual GPC</p> <p>23          data from the seven-year dog study, and we've got</p> <p>24          the -- plus or minus the range of the data on top of</p>	<p>1           crack depths were in the dog study, right? Wouldn't</p> <p>2           the proper procedure or analysis be to analyze the</p> <p>3           depth of the cracks on the dog study if you're using</p> <p>4           the GPC data from the dog study?</p> <p>5           MR. HUTCHINSON: Object to form.</p> <p>6           Compound.</p> <p>7           THE WITNESS: Well, you can -- that</p> <p>8           would actually wind up being more favorable.</p> <p>9           Because if you look at Dr. Iakovlev's</p> <p>10          relationship that he's developed between time</p> <p>11          and crust thickness, it goes -- gets larger</p> <p>12          as a function of time. And I believe off of</p> <p>13          memory, he plots something in the seven-year</p> <p>14          mark that might be on the order of 6 or 7</p> <p>15          microns.</p> <p>16          So I'm actually being generous with my</p> <p>17          computation here. If I were to actually use</p> <p>18          that data, I would look worse, the</p> <p>19          computation would look worse in terms of</p> <p>20          showing that, yes, I can discern with</p> <p>21          molecular weight, even though it's a bulk</p> <p>22          analysis, if I have a crust that that's</p> <p>23          thick.</p> <p>24          Q (By Mr. Thornburgh) Okay. And then you are</p>
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<p>1           the 61,000 mass units, and we're comparing that to a</p> <p>2           computed molecular weight that you would get from a</p> <p>3           combination of having a crust and a core that's not</p> <p>4           degraded. So we're doing that calculation. We're</p> <p>5           seeing what the change in the molecular weight would</p> <p>6           be, and then we're comparing it against the actual</p> <p>7           molecular weight data from the dog study.</p> <p>8          Q Okay, so --</p> <p>9          MR. HUTCHINSON: Dan, excuse me, let me</p> <p>10         give you just a heads-up. We're coming close</p> <p>11         to seven hours.</p> <p>12         MR. THORNBURGH: Yeah, no, I'm almost</p> <p>13         done, but this is an important --</p> <p>14         MR. HUTCHINSON: Okay.</p> <p>15         MR. THORNBURGH: -- issue.</p> <p>16         THE WITNESS: Okay.</p> <p>17         MR. HUTCHINSON: I'm just going to tell</p> <p>18         you, though, that I am going to call the</p> <p>19         deposition at seven hours, so we're getting</p> <p>20         close --</p> <p>21         Q (By Mr. Thornburgh) But you don't know --</p> <p>22         MR. HUTCHINSON: -- as a courtesy to</p> <p>23         you.</p> <p>24         Q (By Mr. Thornburgh) You don't know what the</p>	<p>1           using just one data point from the Bellew explant for</p> <p>2           the nano thermal analysis?</p> <p>3           A I am not. If you go back and read Bellew,</p> <p>4           you'll see that he sampled -- just let me finish -- he</p> <p>5           sampled a number of different locations, he gets a</p> <p>6           range of 121 to 127 C in his data, and we've basically</p> <p>7           taken the nominal average of that.</p> <p>8          Q But those were different treated specimens,</p> <p>9           right, so some specimens were treated -- weren't</p> <p>10         treated at all with any reagents, some were treated</p> <p>11         with sodium hypochlorite, and so there was a big change</p> <p>12         in the drop of the thermal melt point from a, you know,</p> <p>13         nontreated mesh sample versus a sample treated with</p> <p>14         sodium hypochlorite?</p> <p>15         A Okay, let's break --</p> <p>16         MR. HUTCHINSON: Objection, compound.</p> <p>17         THE WITNESS: Let's break that down. If</p> <p>18         that's true -- I haven't had a chance to go</p> <p>19         back and verify that -- if that's true, the</p> <p>20         range of the data that I just cited to you is</p> <p>21         accurate, 121 to 127, regardless of</p> <p>22         treatment, nontreatment, et cetera, from the</p> <p>23         Bellew mesh. It's a 6-degree window. I've</p> <p>24         used the nominal average. There's not a lot</p>

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<p>1 of variation there. This computation is  2 solid based on the estimates that we've used  3 from your expert reports.</p> <p>4 Q (By Mr. Thornburgh) The analysis that you  5 did of the histopathology of -- you wanted to prove a  6 couple theories wrong of Dr. Iakovlev's, I think is  7 what you stated earlier?</p> <p>8 A Yes.</p> <p>9 Q And you -- so you had some -- you purposely  10 degraded some samples of pristine TTVT devices, right?</p> <p>11 A Of pieces of mesh, of pieces of TTVT mesh,  12 yes, we did.</p> <p>13 Q Okay. And you used ultraviolet radiation?</p> <p>14 A We did, we used a QUV chamber.</p> <p>15 Q What was the depth of the cracked surface  16 layer of that purposely degraded polypropylene suture?</p> <p>17 A I would estimate it to be 20 to 25 microns.</p> <p>18 I'm using Figure 15 in that report as a reference.</p> <p>19 MR. HUTCHINSON: Dan, two or three more  20 minutes now.</p> <p>21 MR. THORNBURGH: Come on.</p> <p>22 MR. HUTCHINSON: You had seven hours.</p> <p>23 MR. THORNBURGH: How long have we been  24 on the record?</p>	<p>1 Q Who actually did the staining of these  2 slides?</p> <p>3 A That would be the firm Histon,  4 H-I-S-T-I-O-N, in Everett, Washington.</p> <p>5 Q Why did you refer it to Histon in Everett,  6 Washington?</p> <p>7 A We wanted to use a lab that has core  8 competencies in histological staining, and this is  9 something that they've been doing for, I believe, 20 or  10 25 years.</p> <p>11 Q And so the images of the ultraviolet  12 radiation staining are on page 15; is that correct?</p> <p>13 A For the QUV -- for the UV oxidized mesh,  14 correct.</p> <p>15 Q Why are the images so blurry?</p> <p>16 A Well, it's because -- let me explain to you,  17 these samples are very, very thin. They're microtomed  18 samples, and you have to remember that the original  19 sample is a piece of mesh that is embedded in paraffin  20 or resin so you could do the microtoming process.  21 There are no guarantees, as we talked about in the  22 report, that as I slice a fiber that's embedded, that  23 I'm going to get a perfect circle for a cross-section,  24 because the mesh itself might be slightly misaligned</p>
<p style="text-align: center;">Page 291</p> <p>1 THE VIDEOGRAPHER: I have to add it up.  2 Sorry.  3 (Discussion off the written record.)</p> <p>4 THE VIDEOGRAPHER: Six hours and forty  5 minutes.</p> <p>6 MR. THORNBURGH: Twenty minutes.</p> <p>7 Q (By Mr. Thornburgh) All right, so you took  8 the --</p> <p>9 MR. HUTCHINSON: We started at 9:30.</p> <p>10 Q -- TTVT pristine samples. You did ultraviolet  11 radiation. And then what did you do?</p> <p>12 A We also -- we also did another set of samples  13 in parallel when we chemically oxidized it.</p> <p>14 Q Yep. And then after you did chemical  15 oxidation and ultraviolet radiation oxidation, what did  16 you do with those samples?</p> <p>17 A We placed those samples in an embedding  18 media, both paraffin and a resin, to basically create a  19 solid specimen that we could then microtome, and then  20 those samples were microtomed to create thin  21 specimens -- that's very common in histology, as I've  22 learned -- to place those on glass slides. And then  23 they were subsequently stained per the protocol that  24 we've listed inside the report.</p>	<p style="text-align: center;">Page 293</p> <p>1 with the microtome blade, and there's nothing you can  2 do about that. That's the nature of the process.</p> <p>3 And because of that, the specimen may not  4 ultimately lie perfectly flat on the glass slide, and  5 if it's not perfectly flat at these -- I shouldn't say  6 perfectly flat. The specimen itself might have a bias  7 to it, the cut might be biased. And because of that,  8 you will have different fields of view that come into  9 focus a little bit differently from neighboring  10 sections. So it's just -- it's the nature of trying to  11 look at microtome specimens in this manner at higher  12 magnifications.</p> <p>13 Q And the staining and the microphotographs  14 were all done at a different lab?</p> <p>15 A These were all done at Histon, correct.</p> <p>16 Q Okay. And you sent the mesh specimens to  17 Histon after you had oxidized them or degraded them  18 through ultraviolet radiation?</p> <p>19 A That's correct.</p> <p>20 Q And how many samples did they stain?</p> <p>21 A Oh, several. I'd have to look at the raw  22 data.</p> <p>23 Q You only have a picture of one, is that  24 right, or two?</p>

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<p>1 A We've got -- we have one represented here, 2 No. 9, on Figure 9, and then we have the -- 3 Q Figure 11? 4 A -- exemplar as Figure 11. 5 Q That's unoxidized, right? 6 A That is. That's unoxidized. And then 7 chemically oxidized is Figures 6 and 7. 8 Q How many -- how many images, photo 9 micrographs were taken of the QUV-treated mesh samples? 10 A I don't recall. We'd have to look at the raw 11 images that are on the thumb drive I gave you. 12 Q Who picked out the samples to -- or the 13 microphotographs to use in this report? 14 A I did. 15 MR. THORNBURGH: I have one hour and 16 twenty minutes left on the record. Thanks. 17 MR. HUTCHINSON: Huh? That ain't right. 18 We're off the record real quick. 19 THE VIDEOGRAPHER: Off the video? 20 MR. HUTCHINSON: That's not -- yes. 21 That's not right. We started -- 22 THE VIDEOGRAPHER: We are now going off 23 the video record. The time is currently 24 5:43 p.m.</p>	<p>1 knowingly degrade it, and see if it stains. 2 The thickness is irrelevant in this -- in 3 this testing, in this experimental approach. 4 We're just trying to say if I have oxidized 5 Prolene, will it stain, and the answer is no. 6 Q (By Mr. Thornburgh) Let me just try to -- so 7 how do you -- how did you calculate or estimate a 8 20-micron crack in this specimen? 9 A We didn't. We didn't. It was just a 10 measurement from looking at micrograph number -- or 11 Figure 9. If you look at the cracks that are 12 penetrating inside the fiber and you use the scale bar 13 to the right, I've estimated it about 20 to 25 microns 14 in depth. And again, that depth is really irrelevant 15 here. It's not -- it's not part of the study. 16 Q Okay, so you're measuring from the outside of 17 this image to the core? Is that the core right there? 18 A I wouldn't call it the core. I'm just trying 19 to estimate -- you asked me how deep the cracks were, 20 at least that's what I thought you did, and I just 21 looked at these figures and I used the scale bar; and 22 seeing the cracks that radiate inward, I'm saying that 23 they're about 20 to 25 microns in depth. 24 Q Have you -- you've looked at Dr. Iakovlev's</p>
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<p>1 (Off the record.) 2 THE VIDEOGRAPHER: We are now back on 3 the video record. The time is currently 4 5:44 p.m. 5 Q (By Mr. Thornburgh) Who performed the 6 process of doing the QUV degradation? 7 A Dr. Benight. Dr. Benight, at my direction. 8 Q And how did she determine to stop the QUV 9 process? 10 A It's pretty straightforward. If you look at 11 the micrographs on Figure 2, we saw clear evidence of 12 cracking on the outside surface. And knowing that 13 those are pristine fibers to begin with, they're in a 14 QUV environment, when you see this degree of cracking, 15 it was a -- it was a visual observation that said, 16 okay, we've definitely degraded it, it's done. 17 Q But if you understood that the average crack 18 depth is 4 microns, according to your analysis that you 19 did in the prior section a moment ago, why would you 20 stop the degradation process at 20 microns? 21 MR. HUTCHINSON: Object to form. 22 THE WITNESS: Look, all I'm trying to 23 do -- let's not overcomplicate this. All I'm 24 trying to do is take a Prolene specimen,</p>	<p>1 report, right? 2 A I have. 3 Q And -- 4 A I'm sorry. 5 Q -- you would agree with me that the -- 6 MR. HUTCHINSON: Hey, guys, y'all are 7 talking over each other. 8 Q (By Mr. Thornburgh) Okay. You've looked at 9 Dr. Iakovlev's report? 10 A I just wanted to ask a clarifying question. 11 For the consolidated cases? 12 Q Yeah, sure. 13 A I have. 14 Q And you've looked at his micrograph images, 15 right? 16 A I have. 17 Q And why is the magnification of the pictures 18 that you have in your report much lower than 19 Dr. Iakovlev's images? 20 A Well, I think it goes back to what we just 21 talked about. We had seen that the amount of cracking 22 was around 20 to 25. We know that that region, because 23 the cracks exist, is oxidized and felt it was in our 24 best interests to be able to show that swath of</p>

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<p>1 material that has the cracks in it in these  2 micrographs. So we were just kind of showing the  3 region that's clearly been oxidized by the presence of  4 crack.</p> <p>5 Q If you look at Figure 2, which is the SEM  6 image of the ultraviolet degraded specimen, you can see  7 the big chunks and -- of the mesh peeling up from the  8 surface -- I mean from the core, right?</p> <p>9 MR. HUTCHINSON: Object to form.</p> <p>10 THE WITNESS: You can see some peeling  11 up, correct.</p> <p>12 Q (By Mr. Thornburgh) Why can't I see any  13 peeling on the image in Figure 9?</p> <p>14 A Because you're looking at the length of the  15 fiber here in Figure --</p> <p>16 Q I'm sorry, Figure 9.</p> <p>17 A Sorry. In Figure 9, you're looking at a  18 cross-section. So it just so happens to be that in  19 this particular cross-section that was -- that was  20 performed by microtoming, we didn't happen to catch  21 that region that had some curling to it.</p> <p>22 Q Did you -- in any of your micrographs, did  23 you catch any images of the peeling of the surface  24 layer?</p>	<p>1 Q What was the automated stainer?</p> <p>2 A It would -- it would be in the -- it would be  3 in the files of the notes.</p> <p>4 Q Is it --</p> <p>5 A I don't have the name of it.</p> <p>6 Q Is this what you were discussing earlier,  7 that it was impossible to hold cross-sectioned mesh on  8 the slides in a vertical position?</p> <p>9 A Repeat that. I'm sorry.</p> <p>10 Q Would you agree that it's impossible to hold  11 the cross-sectioned mesh on slides in the vertical  12 position using the automated stainer?</p> <p>13 A No, I wouldn't agree with it. That's exactly  14 what we did. We mounted the microtomed specimens onto  15 the slides. Some of them will fall off, and those are  16 just -- those are just not used. The ones that survive  17 the staining process are the ones that we then imaged.</p> <p>18 Q So some of the mesh specimens fell off of  19 the -- of the stainer?</p> <p>20 A Correct. And that will happen and that's why  21 you make multiple samples, and the ones that survive  22 the whole process are the ones that you then utilize  23 for microscopy.</p> <p>24 Q Did you use vertical?</p>
<p style="text-align: center;">Page 299</p> <p>1 A Oh, I don't recall.</p> <p>2 Q Can you see a skin-core difference, in other  3 words, can you see a skin of degraded polypropylene and  4 a core of undergraded polypropylene in your other  5 images?</p> <p>6 MR. HUTCHINSON: Object to form.</p> <p>7 Q (By Mr. Thornburgh) Or is that what we're  8 seeing here?</p> <p>9 A You can see it -- you can see it here. I --</p> <p>10 MR. HUTCHINSON: Object to form.</p> <p>11 THE WITNESS: I appreciate it's a little  12 but difficult to see, but basically where the  13 cracks end, the tips of the cracks, if you  14 will, that are emanating inward, that region  15 would be the degraded region, and then  16 everything inboard of where those cracks stop  17 would arguably be the so-called core.</p> <p>18 Q (By Mr. Thornburgh) So you agree that this  19 degraded polypropylene has a degraded core or degraded  20 bark, right?</p> <p>21 A I agree that the outer layer of this fiber  22 has suffered from UV degradation.</p> <p>23 Q Did you use any automated stainer?</p> <p>24 A We did.</p>	<p style="text-align: center;">Page 301</p> <p>1 A Yes, vertical orientation.</p> <p>2 Q Okay. Do you understand that the only way to  3 cross -- to cross -- to stain a cross-sectioned mesh is  4 to do it on a horizontal tray?</p> <p>5 A I don't agree with that.</p> <p>6 Q You didn't actually perform the staining?</p> <p>7 A No, but I witnessed it.</p> <p>8 Q Who up there -- was it -- was it Benight?</p> <p>9 A Mrs. -- yeah, Dr. Benight.</p> <p>10 Q So Benight did it and she did it on the  11 vertical position, right?</p> <p>12 A Correct. And for the record, we know the  13 staining process works because that's why we used the  14 positive control that you see on page 11. Same  15 orientation, same staining bath, same staining process.</p> <p>16 Q Did you do any manual staining?</p> <p>17 A We did not.</p> <p>18 Q How did you wash the sections?</p> <p>19 A It says it's in the -- it's right in the  20 protocol. I defer to pages 20 and 21. Twenty is the  21 alcohol rinsing and dehydration before you mount it in  22 paraffin or before you mount it in the resin. And then  23 page 21 -- excuse me. This is all just for paraffin.  24 And then page 21 has the sequence of the various washes</p>

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<p>1 and baths and the associated times.</p> <p>2 Q And if you look at Figure 8, you have another</p> <p>3 Prolene mesh that was chemically oxidized using the</p> <p>4 Guelcher protocol?</p> <p>5 A Yes.</p> <p>6 Q Why is that image so blurry?</p> <p>7 A It's the -- it's the same answer. It's the</p> <p>8 fact that you're trying to take a micrograph of a</p> <p>9 cylinder and your field of view is very limited to</p> <p>10 focus on. It's not an SEM image where you have the</p> <p>11 benefit of depth of field. This is with light -- with</p> <p>12 a light microscope and you had just don't have that</p> <p>13 same depth of field.</p> <p>14 Q You saw cracking in SEM, right --</p> <p>15 A For the --</p> <p>16 Q -- obviously?</p> <p>17 A For the QUV sample, we did, correct.</p> <p>18 Q Okay. If you saw cracking in SEM, why can't</p> <p>19 you see it in the light microscopy?</p> <p>20 A We did not see any cracking in -- are we</p> <p>21 talking about the chemically stained sample?</p> <p>22 Q Yeah.</p> <p>23 A We did not see any surface cracking on the</p> <p>24 chemically stained specimen.</p>	<p>1 between those two images in Figure 9. One is with</p> <p>2 traditional light microscopy; one is using polarized</p> <p>3 light.</p> <p>4 Q Do you agree that the tangentiality of</p> <p>5 sectioning can cause an overlap between nondegraded and</p> <p>6 degraded layers?</p> <p>7 A Can you describe what you mean by</p> <p>8 "tangentiality"?</p> <p>9 Q No.</p> <p>10 A I'm sorry, then I'm going to have a hard time</p> <p>11 answering that.</p> <p>12 Q In the QUV-treated mesh specimens, when you</p> <p>13 did the staining, did you put it in some sort of</p> <p>14 protein first?</p> <p>15 A No, we did not.</p> <p>16 Q So you just -- you have the material, you put</p> <p>17 it on a slide, I assume?</p> <p>18 A Ultimately, after you embed it.</p> <p>19 Q After you embed it and then slice it?</p> <p>20 A And slice it and then it goes on the slide,</p> <p>21 correct.</p> <p>22 Q And then you stain it without any protein or</p> <p>23 anything on the slide; is that correct?</p> <p>24 A That is correct, there is no protein involved</p>
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<p>1 Q Okay. And on the --</p> <p>2 A Sorry, in the chemically oxidized specimen.</p> <p>3 Q On the ultraviolet radiation degraded mesh,</p> <p>4 we see cracking in the SEM, but we don't see it in the</p> <p>5 light microscopy, or is that where you're saying those</p> <p>6 are cracks but you just -- they're just blurred?</p> <p>7 A No, I'm not saying that. I'm saying that</p> <p>8 with the chemically oxidized specimen, as we viewed</p> <p>9 them in SEM, we did not see any surface cracking that</p> <p>10 was similar to what we saw with the QUV samples.</p> <p>11 Q This is your light microscopy on the</p> <p>12 ultraviolet radiated mesh, right?</p> <p>13 A Correct.</p> <p>14 Q And --</p> <p>15 MR. HUTCHINSON: Dan, so the record is</p> <p>16 clear, you're talking --</p> <p>17 MR. THORNBURGH: Figure 9.</p> <p>18 MR. HUTCHINSON: Okay.</p> <p>19 THE WITNESS: Yeah, right-hand side</p> <p>20 Figure 9 he's pointing to.</p> <p>21 Q (By Mr. Thornburgh) Figure 9 is the -- is</p> <p>22 the light microscopy, right?</p> <p>23 A It's -- yes, with polarized light, correct,</p> <p>24 but it's light microscopy. And that's the difference</p>	<p>1 in this experiment whatsoever.</p> <p>2 Q So no protein could be absorbed into the</p> <p>3 degraded bark or the degraded layer, right?</p> <p>4 A Correct.</p> <p>5 Q If some protein was absorbed into the cracks</p> <p>6 in the mesh and then you used H&amp;E staining, those</p> <p>7 stains could penetrate where the protein would be</p> <p>8 located; is that correct?</p> <p>9 A Correct, but that would be inconsistent with</p> <p>10 the micrographs I have seen from Dr. Iakovlev.</p> <p>11 Q In what way?</p> <p>12 A There's plenty of regions where there's no</p> <p>13 local crack for that penetration that you just</p> <p>14 hypothetically described to stain a particular region.</p> <p>15 There's plenty of regions within his micrographs that</p> <p>16 are just pure crust with no crack and they stain.</p> <p>17 Q One of your -- one of your theories is that</p> <p>18 proteins get absorbed into the polymer cracks, right?</p> <p>19 MR. HUTCHINSON: Object to form.</p> <p>20 Q (By Mr. Thornburgh) Underneath the surface</p> <p>21 or within the surface, which causes the plasticization?</p> <p>22 A There are -- there's a potential for proteins</p> <p>23 and other molecules with carbonyl functionality to be</p> <p>24 absorbed by the material.</p>

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<p>1       Q    Okay.</p> <p>2       A    Yes.</p> <p>3       Q    So -- but you're saying that Dr. Iakovlev's</p> <p>4       H&amp;E staining and analysis of explanted mesh material is</p> <p>5       incorrect to demonstrate that the outer layer is</p> <p>6       degraded bark, right?</p> <p>7       A    He is -- let's be clear on this. He is using</p> <p>8       his staining technique to unequivocally say the</p> <p>9       material is degraded from oxidation. And this study</p> <p>10      completely contradicts and by no way supports that</p> <p>11      theory. If you have an oxidized material,</p> <p>12      polypropylene -- or, excuse me, Prolene, it does not</p> <p>13      stain. He hasn't talked about any secondary mechanism</p> <p>14      of staining. He's unequivocally on the record saying</p> <p>15      the degraded oxidized Prolene stains, and it does not.</p> <p>16      Q    Do you know how long it takes for the -- how</p> <p>17      long does it take for degradation, outer degradation,</p> <p>18      skin, of a Prolene fiber to degrade to a thickness</p> <p>19      that's detectable by light microscopy? Let me ask that</p> <p>20      question again.</p> <p>21      A    Okay.</p> <p>22      Q    Do you know how long it would take -- at what</p> <p>23      depth of the degraded bark can the light microscopy</p> <p>24      detect the degraded layer of the protein fibers?</p>	<p>1       Q    (By Mr. Thornburgh) Let me hand you what</p> <p>2       I've marked as Exhibit 19. Have you seen this document</p> <p>3       before?</p> <p>4       A    I have.</p> <p>5       Q    This is from 1984?</p> <p>6       A    It is.</p> <p>7       Q    And in this report, they talk about different</p> <p>8       potential causes of the degraded outer layer of the</p> <p>9       fibers or the morphological changes in the fibers,</p> <p>10      right?</p> <p>11      MR. HUTCHINSON: Object to form.</p> <p>12      Q    (By Mr. Thornburgh) So it's dated</p> <p>13      November 5th, 1984. It's titled "Prolene</p> <p>14      Microcracking," right?</p> <p>15      A    Right. You just gave a summary of the</p> <p>16      document. I'm just trying to see if I agree with your</p> <p>17      summary. Why don't we just say this: The document</p> <p>18      speaks for itself in terms of what it purports to say.</p> <p>19      Q    The document summarizes experimental findings</p> <p>20      related to microcracking and related to Prolene</p> <p>21      sutures, right?</p> <p>22      A    Correct.</p> <p>23      Q    The cracks are predominantly transverse; do</p> <p>24      you see that?</p>
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<p>1       A    I'm sorry, I'm lost in the question. Maybe</p> <p>2       we can do that again.</p> <p>3       Q    Sure. The only staining of the mesh would be</p> <p>4       at 20 microns, is that right, 20 microns?</p> <p>5       A    Not at the 20-micron level. I mean, we</p> <p>6       know -- just basic polymer science tells us that if</p> <p>7       I've got QUV lights bombarding the specimen to degrade</p> <p>8       it like we see here, that the material that's at the</p> <p>9       very, very, very outermost layer is probably going to</p> <p>10      suffer more oxidation, more degradation than stuff</p> <p>11      that's more towards the fiber core. So there will be</p> <p>12      a -- there's probably a gradient of UV degradation</p> <p>13      across that crack thickness that we see. I don't know</p> <p>14      if that answers your question, but --</p> <p>15      Q    Do you remember seeing an animal -- an</p> <p>16      internal Ethicon study that said the way to</p> <p>17      definitively determine whether or not the outer layer</p> <p>18      of the explanted Prolene fibers is degradation is to do</p> <p>19      intentional oxidation of pristine samples to see if</p> <p>20      there's a skin-core morphology that's created?</p> <p>21      A    Yeah, I recall some -- maybe Dr. Moy. I</p> <p>22      recall that somewhere. Sure.</p> <p>23      (Discussion off the written record.)</p> <p>24      (Exhibit 19 marked for identification.)</p>	<p>1       A    I do.</p> <p>2       Q    No. 2, "Severity (depth and density) and</p> <p>3       location of the cracks are nonuniformly distributed</p> <p>4       along the suture lengths and do not correlate obviously</p> <p>5       with areas of high stress." See that?</p> <p>6       A    I do.</p> <p>7       Q    And then No. 3, "The severe" -- "In severe</p> <p>8       cases, the cracks lead to the production of a separated</p> <p>9       layer of seemingly uniform thickness and a relatively</p> <p>10      clean under surface." No. 4, "Also in severe cases,</p> <p>11      secondary longitudinally cracks give rise to brick-like</p> <p>12      structures."</p> <p>13      A    Correct. Just all visual observations of the</p> <p>14      cracked outer layer.</p> <p>15      Q    And if you look at the "Laboratory Studies,</p> <p>16      Experimental and Results," it says, "The following</p> <p>17      experiments were carried out to test whether</p> <p>18      microcracking results from physical (environmental</p> <p>19      stress cracking) or chemical (oxidation) degradation</p> <p>20      and whether the discrete thickness of the crack layer</p> <p>21      arises from natural separation point in the fiber</p> <p>22      (skin-core morphology)." Did I read that correctly?</p> <p>23      A    You did.</p> <p>24      Q    It says environmental stresses cracking,</p>

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<p>1 talks about the process of environmental stress  2 cracking, says that polypropylene fibers have been  3 shown to develop crazes at elongations as low as  4 5 percent. It talks about the hypothesis that  5 long-term exposure to a sensitizing agent in vivo may  6 result in environmental stress cracking and formation  7 of microcracks, right?</p> <p>8 A That's what it says. Let's -- while we're  9 here, let's just hit this. There's absolutely no  10 evidence to suggest that ESC is taking place in these  11 fibers.</p> <p>12 Q Well, a drop in the DSC --  13 MR. HUTCHINSON: ESC.</p> <p>14 Q -- a drop in the DSC results, right, would be  15 indication of amorphous zones that would make a  16 polypropylene suture susceptible to environmental  17 stress cracking, right?</p> <p>18 MR. HUTCHINSON: Object to form.</p> <p>19 THE WITNESS: Environmental stress  20 cracking is a physical phenomenon. It is  21 coupled also with embrittlement. We don't  22 see any embrittlement with these fibers  23 whatsoever. There is no evidence of ESC.</p> <p>24 Q (By Mr. Thornburgh) "Oxidation: A great</p>	<p>1 skin-core morphology and discredited it.  2 Q Well, let's -- we're looking, maybe, at the  3 document. I don't know.  4 A We may be.  5 Q Let's take a look at it. See the  6 thermo-optical analysis? They analyzed mesh explants  7 usually in thermo-optical analysis, correct? What is  8 thermo-optical analysis; do you know?  9 A I'm sorry, I'm trying to keep up with you.  10 Where are you?  11 Q I'm on page ETH.MESH.455, page 4.  12 A Yeah, I'm on the same page. Just tell me  13 which --  14 Q "Thermo-optical Analysis."  15 A What paragraph are you on? The bottom  16 paragraph?  17 Q Yep, Figure 7. They did some -- they did  18 some melt-point analysis, right?  19 A Yes, they're visually observing melting of  20 the polymer or the melting of the sample, I should say.  21 So they put the -- they put the -- whatever sample  22 they're going to analyze on a hot stage, typically it's  23 done with a microscope so you can see it, and you're  24 actually visually watching melting as the stage heats</p>
<p style="text-align: center;">Page 311</p> <p>1 body of literature exists regarding oxidative  2 degradation of polypropylene." So it talks about the  3 mechanism of oxidation. We don't have to go through  4 all that, right?</p> <p>5 A Fine.</p> <p>6 Q And then see the "Skin-core Morphology"  7 section?</p> <p>8 A I do.</p> <p>9 Q It says, "If there is no significant  10 difference between the skin region of the fiber,  11 relative to the core, then the thickness of the layer  12 depends only on the extent of whatever reaction is  13 taking place. Skin-core morphologies have been  14 observed in many different types of polymeric fibers.  15 The skin generally results from a temperature gradient  16 experienced by the fiber across the fiber diameter  17 during the quenching step of extrusion. Such a skin  18 layer is generally higher in orientation than the core  19 due to the higher efficiency of heat conduction on the  20 surface. Skin-core morphologies are also generally  21 found in fibers at low to medium degrees of  22 orientation." Did I read that correctly?</p> <p>23 A You did. And somewhere in the universe of  24 Ethicon documents, Ethicon explored the potential for</p>	<p style="text-align: center;">Page 313</p> <p>1 up. Is that what you're asking?  2 Q Yeah. And so they do that and they see upon  3 heating at 150 degrees Celsius, the fiber is taken to  4 its softening point, and contraction along the fiber  5 axis leads to an increase in the diameter of the crack,  6 layer peels off the fiber cleanly. So they're talking  7 about a cracked layer peeling off of the core --  8 MR. HUTCHINSON: Object to form.  9 Q -- at different temperatures, so it's not  10 melting, it's not -- the cracked layer isn't melting  11 with the core is what they're suggesting here, right?  12 MR. HUTCHINSON: Object to form.  13 THE WITNESS: What I'm reading here is  14 that they start to see the fiber melting at  15 150, and it looks like it ultimately reaches  16 its final melting point of 165.  17 Q (By Mr. Thornburgh) Right, but the cracked  18 layer maintains its form; that's what it says?  19 A Correct. So --  20 Q And so they say the --  21 A Hold on. Okay, go ahead.  22 Q "The layer is crosslinked polymer or it is  23 predominantly proteinaceous in nature. If the crack  24 layer is oxidized degradation" -- "degraded</p>

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<p>1 polypropylene, the molecular weight should be lowered, 2 leading to an increase [sic] in melting point -- 3 A Decrease. 4 Q Sorry. "If the crack layer is 5 oxidized/degraded polypropylene, the molecular weight 6 should be lowered, leading to a decrease in melting 7 point of the layer rather than a higher one." 8 A I agree. I agree with that. 9 Q Well, but here they're talking about how 10 the -- an explanted mesh material or Prolene material 11 undergoes thermo-optical analysis, and they start to 12 heat it up and it actually -- the thermal melting point 13 actually rises when protein is attached to the surface? 14 MR. HUTCHINSON: Object to form. 15 Q (By Mr. Thornburgh) Because you had 16 indicated previously that the melt points are 17 mistaken -- being misunderstood because they're 18 actually lowered because of the protein contamination 19 around the fibers. 20 A We're saying -- we're saying two different 21 things. When you're sampling a fiber surface that's 22 been plasticized, like we know happened with Jordi's 23 work, you will see a suppression in melt temperature. 24 That has nothing to do with existence of proteins on</p>	<p>1 Q And we've got to change the tape, but real 2 quick, you looked at Dr. Jordi's analysis and you 3 observed a decrease -- he observed a decrease in the 4 thermal analysis or the melt point of the Prolene 5 samples he analyzed, right? 6 A Correct. 7 Q Not an increase? 8 A Correct. 9 MR. THORNBURGH: Okay. 10 THE VIDEOGRAPHER: We are now -- we are 11 now going off the video record. The time is 12 currently 6:13 p.m. This is the end of 13 Tape No. 5. 14 (Recess taken.) 15 THE VIDEOGRAPHER: We are now back on 16 the video record with Tape No. 6. The time 17 is currently 6:20 p.m. 18 Q (By Mr. Thornburgh) Doctor, we're talking 19 about Exhibit No. 19, and this is the November 5th, 20 1984 memo. And just to sort of summarize what we're 21 looking at, we're trying to determine what the outer 22 layer is that has been observed on explanted Prolene 23 sutures, correct? 24 A That's what we've been talking about,</p>
<p style="text-align: center;">Page 315</p> <p>1 the surface. I'm talking about plasticized Prolene. 2 This document further confirms what we've 3 been saying all along, which is the crust which they've 4 isolated here with their thermo-optical analysis, melts 5 at a higher temperature than the Prolene material. 6 Q In this -- in this one study of this one 7 explant, that's what they're -- that's what they're 8 observing? 9 A Correct, that is correct, in this study. 10 Q And -- 11 A And it contradicts the oxidation and 12 degradation theory a hundred percent. 13 Q Look, the melt point actually increased 14 because of the protein that was encasing this 15 particular explant, right? 16 MR. HUTCHINSON: Is that a question, 17 Dan? 18 MR. THORNBURGH: Yeah. 19 MR. HUTCHINSON: Excuse me. 20 Q (By Mr. Thornburgh) They're observing an 21 increase in melt point in this explant, right? 22 A They are. 23 Q Not a decrease in melt point, right? 24 A Correct.</p>	<p style="text-align: center;">Page 317</p> <p>1 correct. 2 Q And they're hypothesizing, they're saying 3 maybe, you know, ESC is a potential cause for 4 degradation, oxidation is a potential cause, protein or 5 biologic material is a potential cause, skin-core 6 morphology is a potential explanation, in other words, 7 because of the spinning process for -- during the 8 extrusion process of the mesh and the cooling process, 9 that the outer layer is cooled quicker and creates a 10 skin that has more amorphous regions than the 11 crystallinity -- the more crystalline core, right? 12 A Sure, that's a decent summary. 13 Q And there's a recommendation made to try to 14 figure it out once and for all, try to determine and 15 answer the question once and for all, the 16 recommendation by Peter Moy is to do additional -- an 17 additional study to either substantiate or disprove the 18 hypothesis that the outer layer is biologic in origin, 19 and that study would be to do similar transmission 20 electron -- 21 MR. HUTCHINSON: Microscopy. 22 Q -- microscopy examinations on known oxidized 23 Prolene samples to determine whether such a different 24 skin-core morphology could be generated by oxidation.</p>

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<p>1 right?</p> <p>2 MR. HUTCHINSON: Object to form.</p> <p>3 THE WITNESS: That's what it says.</p> <p>4 Q (By Mr. Thornburgh) And did you, in your</p> <p>5 review of the internal Ethicon documents, ever find any</p> <p>6 scanning electron microscopy or transmission electron</p> <p>7 microscopy to determine -- which looked at</p> <p>8 intentionally oxidized Prolene samples?</p> <p>9 A We know that they have actually analyzed</p> <p>10 oxidized polypropylene samples. We talked about that</p> <p>11 earlier, intentionally oxidized polypropylene samples.</p> <p>12 Whether there were micrographs that accompanied that</p> <p>13 work, I just don't recall.</p> <p>14 Q Yeah, we looked at that earlier. They didn't</p> <p>15 have -- that was 1983. They didn't do it then. Right</p> <p>16 here in 1984, they're saying, "We should intentionally</p> <p>17 oxidize some Prolene sutures and then do scanning</p> <p>18 electron microscopy or some other analysis to determine</p> <p>19 if there's a skin-core phenomenon going on," right?</p> <p>20 A That's what he --</p> <p>21 MR. HUTCHINSON: Object to form.</p> <p>22 THE WITNESS: That's what he says.</p> <p>23 Q (By Mr. Thornburgh) And, in fact, you did</p> <p>24 intentional oxidation using radiation and found a</p>	<p>1 Prolene samples to determine whether such a different</p> <p>2 skin-core morphology could be generated by oxidation."</p> <p>3 You oxidized the Prolene samples using</p> <p>4 ultraviolet radiation, right?</p> <p>5 A Correct.</p> <p>6 Q And the outer layer cracked and some of it</p> <p>7 was peeling away?</p> <p>8 A About 20 microns, 25 microns of cracking,</p> <p>9 correct.</p> <p>10 Q And while the skin was cracking, the core</p> <p>11 remained intact and unaffected, right?</p> <p>12 A Let's look at -- let's be clear about this.</p> <p>13 First of all, it's not clear to me why he thinks that</p> <p>14 that particular study would confirm or deny his</p> <p>15 hypothesis. So that's -- let's leave that here.</p> <p>16 That's something you're going to have to ask Dr. Moy.</p> <p>17 I don't understand why that particular study would be</p> <p>18 necessary to confirm his hypothesis or reject it. But</p> <p>19 if you look at my micrographs on Figure 9, you can see</p> <p>20 the cracked layer. But other than the cracks being</p> <p>21 present, I certainly don't see a discernible skin-core</p> <p>22 morphology developing.</p> <p>23 Q Look at Exhibit 5 -- or Figure 5, which is</p> <p>24 your scanning electron microscopy.</p>
<p style="text-align: center;">Page 319</p> <p>1 skin-core morphology with an outer layer of</p> <p>2 polypropylene surface being degraded, right?</p> <p>3 MR. HUTCHINSON: Object to form.</p> <p>4 Mischaracterizes the tests and the results.</p> <p>5 Q (By Mr. Thornburgh) We talked about it</p> <p>6 earlier. I asked you, "Now, Doctor, there's a</p> <p>7 skin-core morphology here," and you said, "Yes," and I</p> <p>8 said, "The outer layer is degraded and the core has</p> <p>9 remained nondegraded," and you said, "Yes," right?</p> <p>10 A I said there was peeling observed in that one</p> <p>11 micrograph. You said there was a skin-core morphology.</p> <p>12 Q I -- well, the record will speak for</p> <p>13 itself --</p> <p>14 A Okay.</p> <p>15 Q -- but in any event, the scientists in 1984</p> <p>16 were suggesting that a study like yours be done, and</p> <p>17 you did it and you confirmed what they -- their</p> <p>18 findings?</p> <p>19 MR. HUTCHINSON: Object to form.</p> <p>20 Q (By Mr. Thornburgh) Or their -- I mean,</p> <p>21 here's what the language is, right, the language is,</p> <p>22 "An additional study to either substantiate or disprove</p> <p>23 this hypothesis would be to do similar transmission</p> <p>24 electron microscopy examinations on known oxidized</p>	<p style="text-align: center;">Page 321</p> <p>1 A We can, but I just told you I'm referencing</p> <p>2 Figure 9, which is a cross-section, which is a much</p> <p>3 better indication of what's happening inside the</p> <p>4 material than something looking on the outside in. And</p> <p>5 what I'm telling you is that, yes, we can see</p> <p>6 definitive cracks here, but there's no evidence of a,</p> <p>7 quote/unquote, skin-core morphology that's setting up.</p> <p>8 I've got a cracked outer layer and the crack stopped.</p> <p>9 I don't necessarily characterize that as skin-core.</p> <p>10 And secondly, we have to realize what the</p> <p>11 data we have is already telling us. We know, we've</p> <p>12 already confirmed as an original hypothesis, we know</p> <p>13 based on Iak's staining work and our lack of staining</p> <p>14 in our work that the crust contains a biological</p> <p>15 component. It's indisputable. The staining took place</p> <p>16 with Iak. The staining did not take place in our</p> <p>17 deliberately oxidized samples.</p> <p>18 Q Can you see any of the blue granules on</p> <p>19 the -- in the degraded bark or the degraded layer of</p> <p>20 your microphotograph?</p> <p>21 A Sure, I can see the colorants. I can see the</p> <p>22 colorants, sure.</p> <p>23 Q In Dr. Iakovlev's studies, in his</p> <p>24 histopathology, in the degraded outer layer, where it's</p>

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<p>1 clearly cracked, you can see those blue granules within 2 the cracked layer, right?</p> <p>3 A We can. And we've shown that that can be an 4 artifact of the light polarization with the microscopy. 5 If you look at Figure 11B -- and I don't -- it doesn't 6 matter that this is an unoxidized Prolene sample. 7 We're just talking about artifacts from the microscopy 8 techniques. We'll actually be able to show that you 9 can get something that looks like a bark with this 10 gradient of colorants in a sample that's not even 11 oxidized. This is exemplar pristine mesh and we can 12 actually -- playing with the polarization of the light, 13 we can introduce that same mechanism or that same -- 14 those same features, if you will.</p> <p>15 And I know that that might be difficult to 16 understand, so I'm going to help -- I'm going to help 17 you understand it a bit more. If we were to put a 18 second layer out here (indicating), and I'm going to 19 trace it with my pen, and let's just say this had all 20 stained purple like we see with Iak.</p> <p>21 Q Why do you keep on calling him Iak?</p> <p>22 A That's just -- I think that's the 23 one-syllable nickname that I've coined him.</p> <p>24 Q I think that's disrespectful.</p>	<p>1 is oxidized polypropylene, right, you intentionally 2 oxidized it, right --</p> <p>3 A We did.</p> <p>4 Q -- and in the outer layer of the cracked 5 surface are blue granules, right?</p> <p>6 A Correct.</p> <p>7 Q And those blue granules are polypropylene -- 8 or are the dyes within the polypropylene, right?</p> <p>9 A Correct, but none of that region is stained.</p> <p>10 Q But I can see the blue granules in the 11 degraded layer. That's all -- that's my only point. I 12 can see blue --</p> <p>13 A Of course you can.</p> <p>14 Q -- granules --</p> <p>15 A Of course you can.</p> <p>16 Q -- in the stained layer, right?</p> <p>17 MR. HUTCHINSON: Guys, one at a time. 18 Dan, would you restate your question.</p> <p>19 MR. THORNBURGH: Yeah.</p> <p>20 Q (By Mr. Thornburgh) In the intentionally 21 oxidized polypropylene sample that you analyzed, there 22 are blue granules within the degraded polypropylene 23 layer, right?</p> <p>24 A Yes, of course.</p>
<p style="text-align: center;">Page 323</p> <p>1 A Sure. I apologize. Dr. Iakovlev.</p> <p>2 Q How many times have you been published in 3 peer-reviewed journals concerning the degradation of 4 polypropylene fibers?</p> <p>5 A None.</p> <p>6 Q You've been doing it for the last 5 or 10 7 years, correct?</p> <p>8 MR. HUTCHINSON: Hey, guys, stop. Stop. 9 MR. THORNBURGH: Don't call my witness 10 Iak.</p> <p>11 MR. HUTCHINSON: Hey, I'm telling you to 12 stop. Do you understand?</p> <p>13 MR. THORNBURGH: No, listen, he doesn't 14 have to -- he doesn't have to be rude and 15 disrespectful.</p> <p>16 MR. HUTCHINSON: Hey, guys, I'm telling 17 everybody to stop. What I'm going to tell 18 you is if there's a question pending, I need 19 you to answer the question.</p> <p>20 Dan, I don't know if you had a question 21 pending or not, but if you could, ask the 22 question.</p> <p>23 Q (By Mr. Thornburgh) Well, my -- let's just 24 take it to here. If we look at Figure 9, which we know</p>	<p style="text-align: center;">Page 325</p> <p>1 Q And why are they there?</p> <p>2 A Because they were there with the native 3 fiber. They come in with the fiber.</p> <p>4 Q Because the degraded -- because the degraded 5 layer is polypropylene, right?</p> <p>6 A Yes. That's what we've been saying all 7 along. We've deliberately degraded this specimen under 8 QUV conditions; and, of course, the polypropylene and 9 the colorant that's on the outside of the fiber has 10 seen the QUV exposure. The polypropylene degrades; 11 but, I mean, the copper pigment particles still stay 12 there.</p> <p>13 Q Right. And that's similar to the 14 photomicrographs that you've seen in Dr. Iakovlev's 15 expert reports with blue granules, which are part of 16 the polypropylene, which are in the polypropylene 17 material in the outer degraded layer of the explant, 18 right?</p> <p>19 A I have and I --</p> <p>20 MR. HUTCHINSON: Object to form.</p> <p>21 THE WITNESS: I have. And I'm telling 22 you two things, that that is an artifact of 23 his light polarization. We've proven it here 24 if you read through page 16 and 17 and look</p>

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<p>1 at Figure 11. And in addition to that, if  2 you look closely at all of his micrographs  3 with the so-called particles in them, in the  4 crust layer, you see a true gradient across  5 the thickness.</p> <p>6 And so if you get back to the diagram  7 that I was just trying to sketch out with  8 you, if you had a true crust out here -- we  9 have false bark here in Figure B. If I  10 sketch out some true bark or crust to the  11 outside of that and if you can visualize this  12 all being purple or violet, you would  13 actually get the same exact image that Iak  14 has in his pictures, in his micrographs.</p> <p>15 MR. THORNBURGH: His name is  16 Dr. Iakovlev.</p> <p>17 THE WITNESS: I'm sorry. It's late in  18 the day. Dr. Iakovlev. I apologize. I'm  19 not intentionally doing that.</p> <p>20 (Discussion off the written record.)</p> <p>21 (Exhibit 21 marked for identification.)</p> <p>22 Q (By Mr. Thornburgh) I'm handing you Exhibit  23 No. 21, which is a memo from Dr. Lunn, March 23rd,  24 1983. Have you seen this document before? You have</p>	<p>1 can seem them here, right?  2 A I do.</p> <p>3 MR. THORNBURGH: By the way, can we get  4 the original copies of these or better copies  5 of the original three 35-millimeter slides if  6 they're available? I'll send you an email.</p> <p>7 Q (By Mr. Thornburgh) Do you see the arrows  8 that are pointing to the outer degraded bark?</p> <p>9 A I see arrows pointing to what appears to be  10 a -- some sort of cylindrical crust layer, correct.</p> <p>11 Q Turn the page. This is an analysis of  12 another Prolene graft explant, correct? And the  13 finding was that the 5-0 Prolene from Specimen 2 were  14 carefully removed from the graft and tested for  15 breaking strength, BSE, and the results were 54 percent  16 breaking strength maintaining when measured against  17 similar size control?</p> <p>18 A I do.</p> <p>19 Q Okay. So in this explant, the -- unlike what  20 you discussed in the dog study, there was a decrease, a  21 significant decrease in the breaking strength, right?</p> <p>22 A Sure. Two things on that if it's a question.  23 One is, it's one data point; and two is, it's not  24 uncommon, if you get plasticization, to get some</p>
<p style="text-align: center;">Page 327</p> <p>1 It's in your -- on your reliance list at least.</p> <p>2 A My answer is yes. I'm just refreshing my  3 memory. Okay.</p> <p>4 Q And this is another memo concerning the  5 Prolene microcracks, right?</p> <p>6 A It is.</p> <p>7 Q And do you recall this report or this set of  8 reports?</p> <p>9 A I recall reading these documents at some  10 point, yes.</p> <p>11 Q Do you recall that Ethicon back in 1983 did  12 the same histopathology or pathological analysis as has  13 been done by Dr. Iakovlev of explanted Prolene sutures?  14 It says right there on the very first paragraph, "The  15 slides were reviewed by light microscopy using  16 polarized light to help identify the cracking." Do you  17 see that?</p> <p>18 A I do.</p> <p>19 Q And these were explants from human specimens,  20 right?</p> <p>21 A Correct.</p> <p>22 Q Okay. And then if you turn the page just to  23 the next -- the very next page in this exhibit, you'll  24 see photomicrographs, which are poor images, but you</p>	<p style="text-align: center;">Page 329</p> <p>1 reduction in tensile strength. It's not that -- it's  2 uncommon to get a reduction in tensile strength.</p> <p>3 Q Okay. So this is a significant reduction in  4 tensile strength, right?</p> <p>5 A Yeah, but it's not -- it's not ductility. We  6 haven't seen -- I haven't seen anyone complaining that  7 these fibers are breaking in vivo, okay? So the  8 allegations that I've heard is that this material  9 embrittles and this material gets stiff. Those are not  10 tensile strength properties.</p> <p>11 Q Yeah, but you are using the dog study to  12 suggest that the Prolene fibers don't lose significant  13 tensile strength, but when you look at explants from  14 human -- human explants of Prolene sutures, you see  15 significant reduction in tensile strength, correct?</p> <p>16 A Yep.</p> <p>17 MR. HUTCHINSON: Excuse me.</p> <p>18 THE WITNESS: Yep.</p> <p>19 MR. HUTCHINSON: Excuse me. Dan, were  20 you finished with your question?</p> <p>21 MR. THORNBURGH: Yeah.</p> <p>22 MR. HUTCHINSON: Object to form.</p> <p>23 Q (By Mr. Thornburgh) That's what we're seeing  24 here, right?</p>

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<p>1           MR. HUTCHINSON: Object to form.</p> <p>2           THE WITNESS: We're seeing one data</p> <p>3           point that has 54 percent either strength or</p> <p>4           reduction in strength. And what I'm saying</p> <p>5           is that the key physical properties that are</p> <p>6           being maintained, if not being improved, are</p> <p>7           the flexibility and the ductility. The</p> <p>8           tensile strength is still fine, it's still</p> <p>9           plenty fine. Of course, you can supplement</p> <p>10          that with the seven-year dog study, but this</p> <p>11          data point does not confirm that that</p> <p>12          material is oxidizing.</p> <p>13          And for all we know, there could have</p> <p>14          been some sort of surface flaw or something,</p> <p>15          some artifact on the outside of the specimen</p> <p>16          that actually causes it to break a bit</p> <p>17          prematurely. That is not uncommon as well.</p> <p>18          So, you know, you've got to take that data</p> <p>19          point with a grain of salt. And I'm not</p> <p>20          concerned about it even if it is accurate</p> <p>21          without a flaw.</p> <p>22          Q (By Mr. Thornburgh) We're going to look at</p> <p>23          some more data points.</p> <p>24          A Okay.</p>	<p>1           formalin from the time of removal from the patient; the</p> <p>2           others had been allowed to dry. Do you see that?</p> <p>3           A I do.</p> <p>4           Q So the others weren't stored in formalin at</p> <p>5           all, correct?</p> <p>6           A I don't think we can say that for sure based</p> <p>7           on the way that's written.</p> <p>8           Q It says three of the nine had been stored in</p> <p>9           formalin from the time of removal from the patient.</p> <p>10          The others all -- had all been allowed to dry.</p> <p>11          A Correct. It doesn't say -- it doesn't say</p> <p>12          they were never stored in formalin and were allowed to</p> <p>13          dry. It just says that they were allowed to dry.</p> <p>14          Q Well, "The dry samples were examined dry</p> <p>15          (in air). The wet samples were examined mounted in the</p> <p>16          formalin in which they were stored." Right? And you</p> <p>17          see that they are -- the observations show some cracks</p> <p>18          on some of these nine explants?</p> <p>19          A Correct.</p> <p>20          Q The general observations and conclusions on</p> <p>21          the next page was that, "Sutures kept in the wet state</p> <p>22          do not exhibit cracks. Upon drying, cracks appear.</p> <p>23          This was actually observed happening by drying the</p> <p>24          six-year wet on the microscope stage. It is obvious</p>
<p style="text-align: center;">Page 331</p> <p>1           Q Don't worry. See the histological evaluation</p> <p>2          on the next page? There was -- the fibers were</p> <p>3          infiltrated with macrophages and giant cells and</p> <p>4          fibroblasts, and cracking of the suture surface was</p> <p>5          also evident in longitudinal sections of Prolene</p> <p>6          located near the graft fibers. Cracking appeared along</p> <p>7          only one edge of the Prolene and was especially</p> <p>8          prominent when viewed with polarized light.</p> <p>9          A That's what it says.</p> <p>10         Q "Measured against a 5-0 Prolene control, this</p> <p>11         segment had 54 percent strength remaining. Light</p> <p>12         microscopy evaluation of this strand revealed surface</p> <p>13         cracking identical to Sample No. 1," right?</p> <p>14         A That's what it says.</p> <p>15         Q If you go to the document dated March 5th --</p> <p>16         March 25th, 1983. March 25th, 1983.</p> <p>17         MR. HUTCHINSON: And this is all within</p> <p>18         Exhibit 21?</p> <p>19         MR. THORNBURGH: Examination of -- yep.</p> <p>20         Examination of 5-0 and 6-0 cardiovascular</p> <p>21         Prolene sutures.</p> <p>22         THE WITNESS: Yep, here it is.</p> <p>23         Q (By Mr. Thornburgh) There were nine samples</p> <p>24         that were submitted. Three of them had been stored in</p>	<p style="text-align: center;">Page 333</p> <p>1           that the severity of the cracks is related to the</p> <p>2           implantation time." Do you see that?</p> <p>3           A That's what it says.</p> <p>4           Q Now, you've seen the dog study where cracks</p> <p>5           were observed on both the dry and undry samples, right?</p> <p>6           A Yes, I've seen -- yes, we've seen cracks on</p> <p>7           many of the seven-year dog study samples.</p> <p>8           Q And the researchers in the dog study said</p> <p>9           unequivocally that sample preparation did not cause the</p> <p>10          cracking, right? Do you recall seeing that in the</p> <p>11          five-year study?</p> <p>12          A I don't recall. I'm not disputing that</p> <p>13          that's what was written.</p> <p>14          Q You're not going to offer -- you're offering</p> <p>15          opinions that cracking -- or drying or analyzing wet</p> <p>16          samples somehow creates artifact?</p> <p>17          A I'll say I think it's noteworthy that on</p> <p>18          several occasions, Ethicon saw cracks develop when</p> <p>19          samples dried.</p> <p>20          Q Do you know why that was?</p> <p>21          A Well, one theory would be if it's a</p> <p>22          formalin-fixed crust and it's allowed to dry and shrink</p> <p>23          in air, you might get cracking.</p> <p>24          Q What's the refraction index of the media</p>

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<p>1 that's used in scanning electron microscopy or 2 microscopy? How does that influence the ability to 3 observe the physical characteristics on top of a 4 suture; do you know?</p> <p>5 MR. HUTCHINSON: Objection. Compound 6 question.</p> <p>7 THE WITNESS: I'm not sure what you mean 8 by "refractive index" and with regard to SEM, 9 so maybe you could just orient me a little 10 bit more.</p> <p>11 Q (By Mr. Thornburgh) Do you know what -- what 12 is a refractive index of scanning electron microscopy?</p> <p>13 A Refractive index is a -- is a material 14 property. So that basically dictates how light gets 15 diffracted and scattered when light hits a sample. 16 It's like tensile strength of material. It's a 17 physical material property of a material or sample. It 18 has nothing to do with the actual microscopic 19 equipment.</p> <p>20 Q But my question is, the media -- the medium 21 that's used or the solution that's used, if it's a wet 22 sample, can impact your ability to observe the surface 23 layer as a result of this refractive index. You've 24 experienced that, right?</p>	<p>1 A Correct. That's what it says.</p> <p>2 Q "Subsequently, sutures were examined by light 3 microscopy while wet and dry. Histological 4 preparations of Prolene cross-sections in tissue were 5 stained in phloxine." What's phloxine?</p> <p>6 A Phloxine, I believe, is some other type of 7 staining medium.</p> <p>8 Q Stained in phloxine and examined for 9 cracking. "Sample 1 through 5 showed no surface 10 cracking in light microscopic examinations of both 11 explanted sutures or histological sections. Sample 6 12 displayed severe cracking of a 3 to 4.5 micron layer as 13 measured in histological cross-sections.</p> <p>14 "The average breaking strength remaining for 15 sizes 3 was 76.5 percent (range 47 to 93 percent) and 16 for size 4.0 was 98.25 (range was 86 to 110 percent) 17 when compared to similar size controls. Only one 18 length of 5-0 Prolene was available for tensile 19 strength measurements, indicating a 76 percent strength 20 remaining for the seven-year specimen."</p> <p>21 So you see for all of these specimens, there 22 was a range, some of which went as low as 47 percent, 23 right?</p> <p>24 A Correct. For 3-0, that's correct.</p>
<p style="text-align: center;">Page 335</p> <p>1 A If you're --</p> <p>2 MR. HUTCHINSON: Object to form.</p> <p>3 THE WITNESS: No, I have not experienced 4 that in SEM. I have not.</p> <p>5 Q (By Mr. Thornburgh) If you see on May 2nd, 6 1984 --</p> <p>7 A Just give me a page.</p> <p>8 Q It's the -- it doesn't have page numbers.</p> <p>9 Somehow it didn't print with the Bates numbers.</p> <p>10 MR. HUTCHINSON: How come this doesn't 11 have Bates numbers on it?</p> <p>12 MR. THORNBURGH: It just didn't print 13 with them. I don't know.</p> <p>14 MR. HUTCHINSON: But these are 15 documents part of the --</p> <p>16 MR. THORNBURGH: These are documents 17 pulled out of Ethicon's file.</p> <p>18 Q (By Mr. Thornburgh) May 2nd, 1984, the 19 summary evaluation of surface cracking and tensile 20 strengths. Do you see that 1 to 5 -- Samples 1 through 21 5 were received by Dr. Bellingham, Stanford University 22 Medical Center, and had Prolene suture in residence for 23 one to two months [sic] to four years three months 24 postop, sizes were 3-0 and 4-0?</p>	<p style="text-align: center;">Page 337</p> <p>1 Q The "Methods" section on the next page, "Each 2 tissue specimen was removed from the formalin solution 3 and rinsed with distilled water. Samples remained wet. 4 Prolene suture was carefully dissected out of the 5 tissue specimens and kept wet in distilled water until 6 examination could be performed."</p> <p>7 And they were submitted to histological 8 preparations. Do you see that?</p> <p>9 A (No verbal response.)</p> <p>10 Q If you turn the page, it shows the results 11 from the tensile strength that was remaining.</p> <p>12 MR. HUTCHINSON: Objection. Compound 13 question.</p> <p>14 Q (By Mr. Thornburgh) We're talking about the 15 same -- the same explanted material. And it shows that 16 the range was 47 to 110 percent, right?</p> <p>17 MR. HUTCHINSON: Same objection.</p> <p>18 THE WITNESS: Correct.</p> <p>19 Q (By Mr. Thornburgh) Do you see where it 20 says, "Phloxine stain had completely penetrated the 21 cracked layer"? We're talking about section -- 22 histological section of Sample 6, which was the 23 severely cracked explant. "A cracked surface layer 24 measuring 3 to 4.5 microns was seen, accounting for</p>

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<p>1 approximately 8.5 of the total cross-sectional area.  2 This layer was birefringent when examined under  3 polarized light microscopy. Phloxine stain had  4 completely penetrated the cracked layer."</p> <p>5 A Sure. If phloxine stain has an affinity for  6 proteins, then it doesn't surprise me.</p> <p>7 Q "Particles of blue dye were evident within  8 the cracked layer." Do you see that?</p> <p>9 A I do.</p> <p>10 Q Have you seen this before today?</p> <p>11 A I have. Just not fresh in my memory, but I  12 definitely have.</p> <p>13 Q "There was evidence [sic] of migration of  14 particles from the cracked surface layer into the  15 surrounding tissue."</p> <p>16 You've seen that in Dr. Iakovlev's studies  17 where you can actually see in some photomicrographs the  18 dye pigments outside of the cracked layer, right,  19 that's moved out of the Prolene into the tissue? Have  20 you seen those?</p> <p>21 A I have and I --</p> <p>22 MR. HUTCHINSON: Object to form.</p> <p>23 Compound question.</p> <p>24 THE WITNESS: I have and I explained to</p>	<p>1 phloxine stain is completely penetrating the cracked  2 layers, they're seeing particles of blue dyes in --  3 within the cracked layer, and there was no evidence of  4 migration of particles from the cracked surface layer  5 into the surrounding tissue.</p> <p>6 Under "Discussion," it says, "In this study,  7 it was shown that 5-0 Prolene suture in residence  8 within a human vascular graft for seven years displayed  9 surface cracking. The depth of the cracking in Sample  10 No. 6 was 3 to 4.5 microns in thickness, consistent  11 with other specimens. Additional evidence from a  12 seven-year specimen suggests no increase in thickness  13 of the cracked layer over time." And then just read  14 the next sentence for me.</p> <p>15 MR. HUTCHINSON: Object to form.</p> <p>16 (By Mr. Thornburgh) "The cracked layer  17 appeared blue in gross specimens and blue dye particles  18 were evident in histology [sic] sections of the layer.  19 This would indicate that the layer is dyed Prolene  20 polymer and not an isolated protein coating on the  21 strands." Did I read that correctly?</p> <p>22 A You did. However, the phloxine itself could  23 be giving a blue hue. We -- that has not been  24 described as to what the typical observation is in</p>
<p style="text-align: center;">Page 339</p> <p>1 you that when you look at those micrographs  2 carefully, that -- two things. He's imaged  3 it using polarized light, and we've  4 demonstrated that you can get a false bark  5 appearance that will include the dyes in that  6 appearance, in that false bark, from our  7 work.</p> <p>8 And in addition to that, you see a  9 gradient of those particles across this  10 so-called bark or crust layer. So there's --  11 at least there's a -- even if it's not false  12 bark, which I believe it is, that's still  13 unexplained to me that a large portion of  14 that thickness is pigment free.</p> <p>15 Q (By Mr. Thornburgh) Here we have Ethicon's  16 internal scientist doing the same histopathology of  17 explanted Prolene sutures as Dr. Iakovlev has done.  18 They're seeing --</p> <p>19 A I would not characterize it as --</p> <p>20 Q They're seeing --</p> <p>21 MR. HUTCHINSON: Guys, guys, excuse me.  22 I think -- let Dan finish his question.</p> <p>23 THE WITNESS: Sure.</p> <p>24 Q (By Mr. Thornburgh) They're seeing that</p>	<p style="text-align: center;">Page 341</p> <p>1 terms of the hue that results from the phloxine stain.  2 So -- and as a matter of fact, the way that it's worded  3 there might even suggest that appeared blue in gross  4 specimen and blue dye particles were evident.</p> <p>5 Q The blue particles were seen within the  6 cracked layer, right? I mean, I don't understand how  7 you -- are you suggesting that these scientists for  8 Ethicon somehow misunderstood or misinterpreted their  9 histopathology?</p> <p>10 MR. HUTCHINSON: Object to form.</p> <p>11 THE WITNESS: They very well may have.  12 We've talked about the micrograph artifacts  13 that you can create from the -- certain  14 microscopy techniques.</p> <p>15 If you read my report, you also will see  16 that I talk about smearing, okay? And  17 smearing is nothing more than a boundary  18 condition effect where material on the edge  19 of the cut, if you do a microtoming, might  20 smear back on top of itself or smear past the  21 original specimen.</p> <p>22 So you -- we can't rule out, based on  23 what's ruled here, that it isn't a microscopy  24 artifact, and we can't rule out that there</p>

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<p>1        was smearing involved.</p> <p>2        Q (By Mr. Thornburgh) Well, these scientists 3        certainly believed that the cracked layer, which had 4        these blue dye -- which had the blue particles within 5        the cracked layer, was that -- they concluded that it 6        was the Prolene polymer that had degraded on the 7        surface of the fiber and not isolated protein?</p> <p>8        MR. HUTCHINSON: Object to form.</p> <p>9        THE WITNESS: Where do you see that they 10       say degraded?</p> <p>11       Q (By Mr. Thornburgh) I mean, you understand 12       what they're seeing -- or talking about here, right? 13       Look at the histopathology microphotographs. They're 14       analyzing these specimens, the cross-sections of the 15       fibers, and they -- there's this crust or this bark on 16       the outer layer.</p> <p>17       A    Correct.</p> <p>18       Q    And they're trying to determine if it's -- if 19       it is degraded Prolene or protein. And what their 20       analysis found or what they concluded from their 21       analysis, which included staining and microscopy, was 22       that the cracked layer appeared blue in gross specimens 23       and blue dye particles were evident in the sections of 24       the layer that -- which degraded. And so --</p>	<p>1        MR. HUTCHINSON: Actually, yeah, you can 2        answer the question, so finish answering the 3        question.</p> <p>4        MR. THORNBURGH: I said, "Do you 5        understand that," and he said, "Yes."</p> <p>6        MR. HUTCHINSON: Hey, Dan, the witness 7        is going to finish answering his question. 8        Go, Dr. MacLean.</p> <p>9        THE WITNESS: Yes, I understand. 10       However, we have clearly demonstrated they 11       use polarized light here. You can actually 12       see they've got -- labeled it "polarized 13       light." If you view these microtome images 14       with polarized light, you can create the 15       exact same artifact, artificial artifact, 16       artificial false bark as what they're 17       describing there. You can see hue changes 18       and you can see this shadowing effect that 19       takes place that gives appearance of a bark 20       layer. So we have proven that, yes, they 21       could have misinterpreted those artifacts for 22       something that really wasn't there.</p> <p>23       MR. THORNBURGH: Well, that's not -- 24       MR. HUTCHINSON: I'm sorry. Are you</p>
<p style="text-align: center;">Page 343</p> <p>1        A    Is there a question?</p> <p>2        Q    So this would indicate, according to these 3        researchers, that the layer is dyed Prolene polymer and 4        not an isolated protein coating on the strands. Do you 5        disagree with these scientists at Ethicon as well?</p> <p>6        MR. HUTCHINSON: Object to form.</p> <p>7        THE WITNESS: I disagree.</p> <p>8        MR. HUTCHINSON: Compound question.</p> <p>9        MR. THORNBURGH: Let me ask a better 10       question.</p> <p>11       Q (By Mr. Thornburgh) You understand that 12       their --</p> <p>13       MR. HUTCHINSON: Is that withdrawn?</p> <p>14       MR. THORNBURGH: I'll withdraw it.</p> <p>15       MR. HUTCHINSON: All right.</p> <p>16       Q (By Mr. Thornburgh) You understand that 17       their conclusion is that this cracked degraded layer 18       that they see on the surface of the fiber, the outer 19       layer of the fiber, is degraded polypropylene because 20       they can see the blue dye particles within the cracked 21       layer?</p> <p>22       A    Correct. Correct. Can I answer the 23       question?</p> <p>24       Q    Do you disagree --</p>	<p style="text-align: center;">Page 345</p> <p>1        finished?</p> <p>2        THE WITNESS: I'm finished.</p> <p>3        Q (By Mr. Thornburgh) Well, they also found 4        that there was a corresponding loss in tensile 5        strength.</p> <p>6        A    I just explained to you that when you 7        plasticize things -- let me take you to my report 8        because I spelled it out in stage there.</p> <p>9        On page 43 of my report, I take the reader 10       through an original material that's not plasticized, in 11       terms of its tensile properties, to a typical 12       plasticized polymer in the -- in the figure below it.</p> <p>13       And I've noted three things that we've been 14       talking about all day: an increase in 15       ductility/toughness, a reduction in modulus, which was 16       the initial slope of those curves, and a slight 17       reduction or a modest reduction in decreased -- or a 18       decrease in breaking strength. So I'm telling you 19       right here that the loss in tensile strength that you 20       keep describing is accounted for by the material being 21       plasticized.</p> <p>22       Q    What plasticized it? What -- how do you -- 23       what evidence do you have that the material that these 24       scientists at Ethicon were looking at had plasticized?</p>

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<p>1        A Dr. Jordi proved it in the Bellew data. He  2        proved it beyond any doubt with his pyro-MS data that  3        he was able to pull out aliphatic ester molecules from  4        the mesh. And we know basic fundamental polymer  5        science is that those molecules will plasticize -- will  6        plasticize Prolene and polypropylene.  7        Q How do they plasticize polypropylene?  8        A They get inside of the polypropylene matrix  9        or the Prolene polymer matrix and they act as a local  10       lubricant, so polymer chains can now slide past one  11       another readily, and that is basically a softening of  12       the material. And that's exactly what we see here as a  13       result of -- the physical properties that we see are a  14       direct result of that mechanism.  15       Q Did you do any tensile testing of the  16       intentionally oxidized Prolene samples that you looked  17       at?  18       A We did not pull them in tension, correct.  19       Q Why not?  20       A Didn't have to. That wasn't part of our  21       study.  22       Q Did you do any GPC analysis to see if there's  23       a loss in molecular weight?  24       A No.</p>	<p>1        Q And they implanted them in dogs and they  2        explanted them at two intervals, Year 1 and Year 2?  3        A Correct.  4        Q They performed FTIR analysis, right?  5        A They did.  6        Q They performed scanning electron microscopy  7        analysis, right?  8        A Yes, there are SEM micrographs in the  9        literature.  10       Q They did histology, a histology study; is  11       that right? I think it's just discussing the cleaning  12       process, right?  13       A Yes, they did a histological study.  14       Q And in their FTIR analysis where they looked  15       at mesh explants -- well, strike that.  16       If you turn to page 202, again, this is  17       Prolene, this is the same material in the TVT device,  18       right?  19       A That's what it says; it says Prolene.  20       Q Same material that was tested by Jongebloed  21       and the same material that Ethicon's internal  22       scientists have been studying this entire time, right?  23       A That's what's reported.  24       Q And Mary and her colleagues found that,</p>
<p style="text-align: center;">Page 347</p> <p>1        Q One of the documents you discuss -- well,  2        has -- Ethicon was continuing to do internal studies  3        where their scientists were concluding that the mesh  4        had -- the explanted Prolene had degraded, right?  5        A Yes, despite the data to the contrary.  6        Q And outside of Ethicon, there were  7        independent scientists who were also analyzing mesh  8        explants or Prolene or polypropylene explants, correct?  9        A Yes, there was mesh studying going on outside  10       of Ethicon.  11       Q Celine Mary, have you reviewed her  12       publication?  13       A I have.  14       Q Do you recall what specimen was analyzed by  15       Mary and her colleagues?  16       (Exhibit 22 marked for identification.)  17       Q (By Mr. Thornburgh) I'll show you. See the  18       "Materials" section on the bottom right-hand corner of  19       the article?  20       A Yes.  21       Q Okay. And it says that they analyzed PVDF  22       sutures and Prolene sutures manufactured by Ethicon,  23       right?  24       A Correct.</p>	<p style="text-align: center;">Page 349</p> <p>1        "After one and two years of implantation, the surface  2        of retrieved and cleaned PVDF sutures did not appear to  3        be substantially modified. In contrast, the  4        polypropylene sutures explanted one and two years  5        postoperatively showed evidence of surface  6        deterioration, characterized by uniformly spaced  7        circumferential cracking and peeling and flaking of the  8        polymer material in the outmost surface layer," right?  9        A Correct. All visual observations of just  10       cracking, correct.  11       Q And what -- what's your opinion that was  12       observed -- what were they observing here of this  13       material that was cracking and peeling and flaking off  14       of the surface of the Prolene?  15       A What is my opinion of what?  16       Q Yeah. Do you have an opinion as to what  17       these scientists were observing in 1996 -- or 1998  18       during the one- and two-year explant studies?  19       A That they see an outer layer that has cracks  20       in it.  21       Q And they concluded that that cracked outer  22       layer was degraded polypropylene, right?  23       MR. HUTCHINSON: Object to form.  24       THE WITNESS: Correct.</p>

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<p>1       Q (By Mr. Thornburgh) Degraded Prolene?</p> <p>2       A    Correct, again, based on this premise that</p> <p>3       the carbonyl functionality is only indicative of</p> <p>4       oxidation.</p> <p>5       Q    If you turn the page, it says, "It has been</p> <p>6       known that polypropylene is susceptible to degradation</p> <p>7       by several different initiation phenomena, including</p> <p>8       thermal, mechanical, photochemical, radiation,</p> <p>9       biologic" --</p> <p>10      A    I'm sorry, where are you?</p> <p>11      Q    On page 203. Strike it. I'll withdraw that</p> <p>12      question.</p> <p>13      A    Okay.</p> <p>14      Q    So do you disagree with -- you disagree with</p> <p>15      their conclusions, right? If you look at the</p> <p>16      "Conclusions" section, "Visual evidence of surface</p> <p>17      degradation was observed at one and two years for the</p> <p>18      polypropylene," which was the Prolene, "but not the</p> <p>19      PVDF sutures"?</p> <p>20      MR. HUTCHINSON: Object to form,</p> <p>21      compound question.</p> <p>22      Q (By Mr. Thornburgh) "This stress cracking</p> <p>23      phenomenon is believed to be associated with the</p> <p>24      distinct skin-core two-phase structure of oriented</p>	<p>1       Q    And they found 1740 carbonyl band.</p> <p>2       A    Right, which we've talked about all day, that</p> <p>3       there are other reasons why that peak can show up. And</p> <p>4       moreover, that peak shows up in the seven-year dog</p> <p>5       study at seven years, and we know it has no net effect</p> <p>6       on the bulk physical properties.</p> <p>7       So it completely contradicts what they're</p> <p>8       saying here. They're saying that oxidation of</p> <p>9       polypropylene or Prolene translates into reduction in</p> <p>10      material properties. The seven-year dog study</p> <p>11      completely refutes that. We have the carbonyl peak in</p> <p>12      that -- in that study at seven years. We have the same</p> <p>13      micrographs with all the transverse grafting, and the</p> <p>14      physical properties are well within intact. As a</p> <p>15      matter of fact, they're getting better.</p> <p>16      So you can't marry those two things, you</p> <p>17      can't marry those two concepts and say it's degraded,</p> <p>18      but yet my properties are being maintained or</p> <p>19      improved.</p> <p>20      Q    Well, scientists outside of Ethicon have been</p> <p>21      studying the loss of the tensile strength in</p> <p>22      degraded -- in explanted polypropylene, including</p> <p>23      Prolene, and had found that there was significant</p> <p>24      tensile strength --</p>
<p style="text-align: center;">Page 351</p> <p>1       polypropylene monofilaments" --</p> <p>2       MR. HUTCHINSON: I'm sorry, Dan, are you</p> <p>3       finished?</p> <p>4       Q    -- "and points to the likelihood of PVDF</p> <p>5       having superior biostability to Prolene" -- "to</p> <p>6       polypropylene over the long term." Do you disagree</p> <p>7       with those conclusions?</p> <p>8       MR. HUTCHINSON: Object to form.</p> <p>9       Q (By Mr. Thornburgh) The conclusion is that</p> <p>10      the polypropylene, the Prolene, had degraded after one</p> <p>11      and two years, right?</p> <p>12      A    Correct, and --</p> <p>13      MR. HUTCHINSON: Object to form.</p> <p>14      THE WITNESS: They're making that</p> <p>15      assessment, they're drawing that conclusion</p> <p>16      based on visual observations. I can't look</p> <p>17      at a fiber -- I can't look at any material</p> <p>18      and, just because it's cracking, say it's</p> <p>19      degraded. We've talked about that all day</p> <p>20      long.</p> <p>21      Q (By Mr. Thornburgh) Well, they also did</p> <p>22      scanning electron microscopy.</p> <p>23      A    Correct. It's the same -- it's the same</p> <p>24      argument.</p>	<p style="text-align: center;">Page 353</p> <p>1       A    There's no --</p> <p>2       MR. HUTCHINSON: I'm sorry. Objection.</p> <p>3       Compound question.</p> <p>4       Q (By Mr. Thornburgh) You -- I mean, you've</p> <p>5       seen -- I mean, if you look at --</p> <p>6       A    There's no --</p> <p>7       MR. HUTCHINSON: I'm sorry. Hey, guys,</p> <p>8       stop it.</p> <p>9       Q (By Mr. Thornburgh) If you look at the Mary</p> <p>10      article --</p> <p>11      MR. HUTCHINSON: Dan, did you withdraw</p> <p>12      that last question?</p> <p>13      MR. THORNBURGH: Yeah.</p> <p>14      Q (By Mr. Thornburgh) If you look --</p> <p>15      MR. THORNBURGH: Yes.</p> <p>16      Q (By Mr. Thornburgh) If you look at the Mary</p> <p>17      article again, if you look on page 203, "In recent</p> <p>18      in vitro and in vivo studies, we have examined the</p> <p>19      physicochemical properties, ease of handling, and</p> <p>20      biocompatibility of a new vascular suture made out of</p> <p>21      PVDF. Compared with polypropylene, the PVDF</p> <p>22      monofilament suture showed better long-term stability</p> <p>23      in vitro by retaining 92.2 percent of the initial</p> <p>24      tensile strength over a nine-year period, whereas</p>

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<p>1 polypropylene retained only 53.4 percent." That's -- 2 what is --</p> <p>3 MR. HUTCHINSON: Sorry. Is that a 4 question?</p> <p>5 THE WITNESS: Is that a question?</p> <p>6 Q (By Mr. Thornburgh) I mean, that's -- so 7 these scientists outside of Ethicon have found that the 8 property -- the properties do change and the tensile 9 strength does decrease in explanted degraded 10 polypropylene sutures.</p> <p>11 A Show me the allegation where somebody is 12 saying loss in tensile strength is causing these 13 methods to be defective.</p> <p>14 MR. HUTCHINSON: All right, guys, I want 15 to ask the videographer how long we've been 16 on the record.</p> <p>17 MR. THORNBURGH: I've got one minute it 18 says.</p> <p>19 MR. HUTCHINSON: No, I'm asking the 20 videographer.</p> <p>21 THE VIDEOGRAPHER: I have to add it up 22 and we'll waste time doing it.</p> <p>23 MR. HUTCHINSON: Okay, you've got one 24 minute?</p>	<p>1 because you see cracking doesn't mean that 2 the underlying polymer is degraded.</p> <p>3 And secondly, if you look at his 4 ultimate conclusion, is that he was not able 5 to determine either way whether the material 6 was truly oxidizing. So -- and that is in 7 lockstep with what I'm telling you, is that 8 there are other reasons why these carbonyl 9 functional groups may be present aside from 10 oxidation.</p> <p>11 He realizes that and that's why he's 12 very careful. There have been people that 13 have taken his literature and taken his 14 findings out of context and saying it's 15 degrading, it's oxidizing. He did not say 16 that, if you read that document properly.</p> <p>17 Q (By Mr. Thornburgh) In the Costello --</p> <p>18 MR. HUTCHINSON: Dan, is this the last 19 question?</p> <p>20 MR. THORNBURGH: Last question.</p> <p>21 Q (By Mr. Thornburgh) In the Costello article, 22 the Costello publication, "Characterization of 23 heavyweight and lightweight polypropylene prosthetic 24 mesh explants from a single patient," you've analyzed</p>
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<p>1 MR. THORNBURGH: I'm going to ask two -- 2 yeah, I'm just --</p> <p>3 MR. HUTCHINSON: Okay.</p> <p>4 MR. THORNBURGH: I'm not going to --</p> <p>5 Q (By Mr. Thornburgh) So you also -- in your 6 report, you disagree with the findings of Clave, right? 7 There you are, right there, 24.</p> <p>8 A I don't -- I --</p> <p>9 MR. HUTCHINSON: I'm going to object to 10 the form to the extent that the findings of 11 Clave is unclear.</p> <p>12 Q (By Mr. Thornburgh) The conclusions of 13 Dr. Clave that the explanted -- the -- strike that.</p> <p>14 You disagree with the conclusions by Clave 15 and his colleagues --</p> <p>16 A I don't. Let's be --</p> <p>17 Q -- that the mesh that was explanted from 18 these women had degraded, mesh explants?</p> <p>19 A Let's be clear about this.</p> <p>20 MR. HUTCHINSON: Object to form.</p> <p>21 THE WITNESS: I disagree with his use of 22 degradation because he's again ascribing it 23 to the fact that he just sees cracking. And 24 we've already talked about the fact that just</p>	<p>1 that, right?</p> <p>2 A I have.</p> <p>3 Q And I'm trying to understand what your --</p> <p>4 MR. HUTCHINSON: Last question.</p> <p>5 Q (By Mr. Thornburgh) Is your opinion that -- 6 maybe it's both. Is your opinion that Costello is 7 wrong in his analysis that these -- that this 8 polypropylene material degraded, or is your opinion 9 that this polypropylene material degraded but it wasn't 10 Prolene?</p> <p>11 A Well, let's start -- let's go backwards. 12 There's certainly no -- there's certainly no indication 13 that he's testing Prolene, so I think -- I guess we can 14 short-circuit this. Whatever conclusions he's drawing 15 on his polypropylene, we can't say carry over one for 16 one with the Prolene material.</p> <p>17 Q Doctor --</p> <p>18 MR. HUTCHINSON: Dan, that was your last 19 question. Do you have one more? I'll do it 20 as a courtesy to you. I'll allow you one 21 more question, and then that's it.</p> <p>22 Q (By Mr. Thornburgh) We've gone through a lot 23 of publications. We've gone through a lot of internal 24 documents. Is it a fair summary of your opinions that</p>

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<p>1 the peer-reviewed publications that we've reviewed,  2 Clave, Costello, Mary, that those peer-reviewed  3 publications that we've reviewed, the authors in those  4 studies reached conclusions that were incorrect or  5 wrong because they somehow misunderstood the behavior  6 of Prolene material in the in vivo environment?</p> <p>7 MR. HUTCHINSON: Object to form.</p> <p>8 THE WITNESS: I would say that there's  9 a -- there's a couple of issues with how you  10 just tried to summarize it. Let me try to  11 clean it up.</p> <p>12 First of all, we just talked about  13 Clave, and there's nothing in his journal  14 article ultimately that is inconsistent with  15 I've been telling you in terms of other  16 reasons why the carbonyl formation --  17 carbonyl functionality could be present.</p> <p>18 As for the other pieces of literature,  19 many of them don't take on Prolene, the  20 specific composition and formulation of  21 Prolene, in their studies. So you need to be  22 careful with that data.</p> <p>23 And the one that does mention Prolene --  24 I think it was the Wood article. You know,</p>	<p>1 MR. THORNBURGH: This is it.  2 MR. HUTCHINSON: Okay. You promise?  3 MR. THORNBURGH: I'm just trying to  4 summarize this -- yep, promise.</p> <p>5 Q (By Mr. Thornburgh) What's -- so we've  6 talked about the outside scientists, the external  7 scientists who published -- who published their  8 research. But what about the internal Ethicon  9 scientists, what is your disagreement with their  10 conclusions from 1983 up until '87, at least -- or,  11 sorry, '92, that the Prolene degraded in vivo?</p> <p>12 MR. HUTCHINSON: Objection. Overly  13 broad, compound.</p> <p>14 THE WITNESS: You just have to look at  15 the totality of the data, and maybe nobody at  16 Ethicon had ever done that, looked at the big  17 picture and pulled all the data in and  18 synthesized it perhaps to the extent that I  19 did. When you look at it, at the very at the  20 end of the day, molecular weight is not  21 changing. So therefore, by definition, we  22 are not having bulk physical property  23 degradation or bulk physical property -- bulk  24 polymer degradation. Excuse me.</p>
<p style="text-align: center;">Page 359</p> <p>1 we just talked about that. And she focuses  2 in on the visual observations of cracking and  3 equating that -- wrongfully equating that to  4 degradation and then simply keying on the  5 carbonyl functionality as evidence of  6 oxidation, which we've talked about is not  7 the sole reason you would have a carbonyl  8 present in the IR spectra.</p> <p>9 So that's my summary of those four.</p> <p>10 Q (By Mr. Thornburgh) The internal  11 documents --</p> <p>12 MR. HUTCHINSON: Dan --</p> <p>13 MR. THORNBURGH: Just real quick.</p> <p>14 MR. HUTCHINSON: Dan --</p> <p>15 Q (By Mr. Thornburgh) What is your  16 disagreement --</p> <p>17 MR. HUTCHINSON: Dan --</p> <p>18 Q -- with the internal Ethicon scientists?</p> <p>19 MR. HUTCHINSON: Excuse me, Dan. Is  20 this your last question?</p> <p>21 MR. THORNBURGH: Yeah. I'm just trying  22 to --</p> <p>23 MR. HUTCHINSON: Now why should I  24 believe you?</p>	<p style="text-align: center;">Page 361</p> <p>1 And then all of the key physical  2 properties that you want for this mesh, in  3 terms of being flexible and in terms of being  4 pliable and having a lot of ductility and  5 stretchiness to it, if you will, are all  6 being maintained and improved.</p> <p>7 So like I said before, this carbonyl  8 that everyone has been focusing on, at the  9 end of the day, it doesn't matter because  10 you've got a -- you've got a material and  11 you've got a mesh that's maintaining or  12 improving all of its key physical properties  13 after seven years.</p> <p>14 Q (By Mr. Thornburgh) In the dog study?</p> <p>15 MR. HUTCHINSON: Dan, that's it. I'm  16 holding you to your promise. We'll take a  17 quick break and then I've got some  18 questions.</p> <p>19 THE VIDEOGRAPHER: We are now going off  20 the video record. The time is currently  21 7:11 p.m.</p> <p>22 (Recess taken.)</p> <p>23 THE VIDEOGRAPHER: We are now back on  24 the video record. The time is currently</p>

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<p>1        7:20 p.m.</p> <p>2                   EXAMINATION</p> <p>3    BY MR. HUTCHINSON:</p> <p>4    Q   Dr. MacLean, my name is Chad Hutchinson. I'm 5    counsel for Ethicon. I have a couple of follow-up 6    questions for you.</p> <p>7        You were asked by Mr. Thornburgh questions 8    about polypropylene and your prior work experience with 9    polypropylene. Do you remember those questions?</p> <p>10      A   I do.</p> <p>11      Q   Tell us about your academic studies about 12    polymers.</p> <p>13      A   Sure. So I have two advanced degrees in 14    polymers, one at the master's level, one at the 15    doctor's -- doctorate level. Both of those advanced 16    degrees, my chosen field of study was polymers, which 17    would include -- a subset of that would include 18    thermoplastic materials, which is what polypropylene 19    is. So I've studied the -- at the academic level, I've 20    studied the structure, property, synthetics, the 21    chemistry of that material, as well as sister polymers 22    to polypropylene.</p> <p>23      Q   And when you say "sister polymers," what do 24    you mean by "sister polymers"?</p>	<p>1        Q   And when you talk about the prevailing 2    structure property relationships, tell us what you mean 3    by that.</p> <p>4        A   Well, if you look at the molecular 5    architecture of the polymer molecule, it gives you -- 6    just by looking at it, it gives you a sense of what its 7    physical properties will be in terms of its melt 8    temperature, its glass transition temperature, what 9    type of mechanical properties I might be able to afford 10    from it.</p> <p>11      Some of these sister polymers that we've 12    talked about are aromatic, they're bigger, they're 13    bulkier in structure, they give you more strength and 14    more stiffness. Whereas polypropylene is a fairly 15    linear, nonaromatic, it's called an aliphatic polymer, 16    and it has its physical properties based on its 17    structure.</p> <p>18      Q   Dr. MacLean, what is a nonlinear aromatic 19    [sic] polymer?</p> <p>20      A   I'm sorry, I missed your question.</p> <p>21      Q   A nonlinear --</p> <p>22      A   Aromatic?</p> <p>23      Q   -- aromatic polymer.</p> <p>24      A   Well, an aromatic polymer is something that</p>
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<p>1      A   I'm talking about linear thermoplastic 2    materials. That can be -- some of them can be 3    semi-crystal and some of them can be amorphous. We've 4    heard terms like ABS, polycarbonate, nylon, polyester, 5    polyethylene, polypropylene. Those are all 6    thermoplastic polymers.</p> <p>7      Q   And have you studied the synthesis of 8    polymers?</p> <p>9      A   I have.</p> <p>10     Q   Have you studied the manufacture of polymers?</p> <p>11     A   I have.</p> <p>12     Q   Have you studied the performance of polymers?</p> <p>13     A   I have.</p> <p>14     Q   And does all that work describe your -- 15    strike that.</p> <p>16     Does all that work you describe relate to 17    polypropylene?</p> <p>18     A   It does.</p> <p>19     Q   How so?</p> <p>20     A   Well, because polypropylene, again, is one of 21    the many materials in the engineering thermoplastic 22    category, and the basic prevailing structure property 23    relationships would apply to polypropylene and all the 24    other sister polymers that I just talked about.</p>	<p>1        has benzene rings in it. We've all seen those 2    six-sided hexagons in some of these chemical 3    structures. That gives the backbone of the polymer 4    some additional steric hindrance and some additional 5    size and bulk, and that translates into bulk physical 6    properties. Polypropylene doesn't have those 7    structures and therefore has its own set of unique 8    properties.</p> <p>9        Q   Why doesn't polypropylene have those 10    structures?</p> <p>11      A   Based on the way it's synthesized, just based 12    on the way the monomers are chosen to make those 13    particular polymers.</p> <p>14      Q   Dr. MacLean, tell us about your prior work of 15    analyzing polypropylene in different applications.</p> <p>16      A   Yeah, sure. There are several polypropylene 17    applications that I've analyzed. And again, some of 18    this work is proactive, some of this work is reactive, 19    failure analysis, root cause investigations. I've been 20    working on one project right now for the last few years 21    involving polypropylene in pressure vessels. So this 22    would be another glass-filled material that we talked 23    about earlier, has a polypropylene base resin, and 24    there's actually potable chlorinated water on the</p>

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<p>1     inside of these vessels. And one of the mechanisms  2     that we were on the lookout for as a potential  3     degradation mechanism is oxidation due to the chlorine  4     environment in the water. There are other -- there are  5     other examples, as well, with polypropylene.</p> <p>6     Q    Have you done any FMEA analysis?</p> <p>7     A    Sure.</p> <p>8     Q    What does that mean?</p> <p>9     A    That stands for Failure Modes and Effects  10    Analysis.</p> <p>11    Q    And have you done, Dr. MacLean, any failure  12    modes analysis of polypropylene?</p> <p>13    A    I've done failure modes and effects analysis  14    on a number of different polymer systems, yes, or a  15    number of different components made out of polymers,  16    which would include polypropylene.</p> <p>17    Q    And give us an example of that, please, sir.</p> <p>18    A    Well, we're doing one, actually, right now.  19    We have a client that makes high-end plastic chairs out  20    of polypropylene. It's a calcium-filled polypropylene  21    material. It is -- some of their chairs are  22    underperforming in the field, and we're trying to use  23    the FMEA technique to understand why those failures are  24    occurring.</p>	<p>1     haven't gotten to yet.</p> <p>2     Q    I'm sorry.</p> <p>3     A    No, that's okay. So another degradation  4     mechanism could be just thermal degradation, just too  5     much heat and chains break down. Another degradation  6     mechanism, or a cracking mechanism, I should say, is  7     environmental stress cracking, which I've studied  8     extensively.</p> <p>9     Q    And, Dr. MacLean, are those degradation  10    mechanisms relevant to the work that you have done in  11    this litigation?</p> <p>12    A    They are.</p> <p>13    Q    Why?</p> <p>14    A    Well, they've -- my knowledge with ESC -- and  15    just let me make sure I'm clear on that. That is not a  16    chain scission, that is not a chemical degradation  17    process. That is a physical process like we've talked  18    about all day long. But I've done extensive work with  19    ESC, and that experience and training has led me to the  20    determination that there's not ESC taking place in  21    these fibers.</p> <p>22    Q    You were asked questions about whether you  23    have ever analyzed an explanted piece of mesh. Do you  24    remember that question?</p>
<p style="text-align: center;">Page 367</p> <p>1     Q    Dr. MacLean, have you studied the degradation  2     modes of the polymers that you're familiar about over  3     the last few years?</p> <p>4     A    I have.</p> <p>5     Q    And what are degradation modes?</p> <p>6     A    Well, we talked about degradation all day  7     long, which is the physical breaking down of the  8     polymer chains, and there's a number of different  9     mechanisms that can get you there.</p> <p>10    Q    Can you give us an example, please?</p> <p>11    A    Sure. Well, we've talked about oxidation all  12    day long. That is one mechanism where you can have  13    energy coming into the polymer. In some cases, that  14    energy can be UV. You can have chemical energy coming  15    in from a chemical environment. You can have energy  16    coming in from thermal or heat environments.</p> <p>17    All of those energies coming into the polymer  18    will break the polymer backbone; and if oxygen species  19    are available, they will attach on to the polymer  20    backbone and cause the oxidation that we've been  21    talking about.</p> <p>22    Q    And have you studied those degradation  23    mechanisms?</p> <p>24    A    I have. And there's other ones that I</p>	<p style="text-align: center;">Page 369</p> <p>1     A    I do.</p> <p>2     Q    Have you?</p> <p>3     A    I have not.</p> <p>4     Q    Why not?</p> <p>5     A    I didn't think I needed to.</p> <p>6     Q    Would that be necessary in reaching your  7     opinions in this litigation?</p> <p>8     A    No. Because as we've talked about all day  9     long, to get to the data that you need to make these  10    determinations on whether oxidation is taking place or  11    some other mechanism is taking place, you have to take  12    these samples and analyze them with instrumentation.  13    And you're looking at surface layers and other physical  14    aspects that are on the microscale, and you just can't  15    pick up -- you can't make any of those determinations  16    with just putting it in this your hands or visualizing  17    it with your unaided eye.</p> <p>18    Q    Would it be duplicative?</p> <p>19    A    It would be duplicative because this whole  20    matter is data -- what I call data rich.</p> <p>21    Q    And what do you mean by "data rich"?</p> <p>22    A    There is data everywhere you look in terms of  23    molecular weight data, melting point data, strength,  24    elongation, modulus data. The list goes on and on.</p>

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<p>1 FTIR data, et cetera. So there's plenty of data that's 2 been generated that can be synthesized and reviewed. 3 Q Would it be necessary to examine or analyze 4 an explanted piece of mesh in order to reach the 5 opinions you have in this litigation?</p> <p>6 A No.</p> <p>7 Q For the reasons we discussed?</p> <p>8 A For the reasons we discussed.</p> <p>9 Q You were asked questions about publishing 10 peer-reviewed literature about polypropylene.</p> <p>11 A Correct.</p> <p>12 Q Do you remember that?</p> <p>13 A Yes.</p> <p>14 Q Dr. MacLean, have you published peer-reviewed 15 literature about sister polymers?</p> <p>16 A I have.</p> <p>17 Q Is that relevant to a discussion about 18 polypropylene polymers?</p> <p>19 A It is.</p> <p>20 Q How so?</p> <p>21 A Like we just talked about, I mean, all of 22 these degradation mechanisms, the analytical tools that 23 everyone has used, the quantification of bulk 24 mechanical properties, et cetera, those will translate</p>	<p>1 was directed at me personally, not at the 2 body of work that we did.</p> <p>3 Q (By Mr. Hutchinson) Did Dr. Benight maintain 4 lab notebooks?</p> <p>5 A She did.</p> <p>6 Q Is it common practice for Dr. Benight to 7 maintain lab notebooks?</p> <p>8 A It is.</p> <p>9 Q Are those lab notebooks that Dr. Benight 10 maintained in the file that was generated and given to 11 the plaintiff's lawyer before the deposition?</p> <p>12 A It was.</p> <p>13 Q And is that Exhibit 5 that is the flash drive?</p> <p>14 A Correct.</p> <p>15 Q And did you give Exhibit 5 to the plaintiff 16 lawyers before this deposition started?</p> <p>17 A I did.</p> <p>18 Q And how many plaintiff lawyers have been here 19 during your seven hours of deposition?</p> <p>20 A There are two.</p> <p>21 Q Did those two plaintiff lawyers have the 22 opportunity to review the flash drive that you gave 23 them before this deposition started?</p>
<p style="text-align: center;">Page 371</p> <p>1 to all of the other polymers that we've talked about, 2 including polypropylene.</p> <p>3 Q Let's switch gears for a minute, okay?</p> <p>4 A Sure.</p> <p>5 Q You were asked questions by Mr. Thornburgh 6 about whether lab notebooks were prepared in accordance 7 with GLP, or good laboratory practices. Do you 8 remember that line of questioning?</p> <p>9 A I do.</p> <p>10 Q Did you personally prepare lab notebooks?</p> <p>11 A I did not personally prepare a lab notebook.</p> <p>12 Q Why not?</p> <p>13 A Because it was done for me at the -- at my 14 direction by Ms. Benight -- or Dr. Benight and the 15 Histon lab.</p> <p>16 Q Is that common practice?</p> <p>17 A It is.</p> <p>18 Q When you were asked whether you personally 19 kept a lab notebook for staining experiences -- 20 experiments, what did you understand that question to 21 mean?</p> <p>22 A I thought --</p> <p>23 MR. THORNBURGH: Objection.</p> <p>24 THE WITNESS: I thought that question</p>	<p style="text-align: center;">Page 373</p> <p>1 A They --</p> <p>2 MR. THORNBURGH: Objection.</p> <p>3 Argumentative. With all due respect, you 4 handed me a flash drive as we're doing the 5 deposition that contains hundreds of 6 material.</p> <p>7 Q (By Mr. Hutchinson) You can answer.</p> <p>8 A We've been -- I've been being deposed with 9 breaks for the last seven-and-a-half hours.</p> <p>10 Q Okay. Did you confirm that the Histon 11 quality control documents are in your file?</p> <p>12 A They are.</p> <p>13 Q And have those files been given to the 14 plaintiff lawyers?</p> <p>15 A They have.</p> <p>16 Q What is the Histon lab?</p> <p>17 A It is the lab that we used to perform the 18 histological staining that we've talked about.</p> <p>19 Q And have you used the Histon lab before?</p> <p>20 A Exponent has, yes, on several occasions.</p> <p>21 Q Why?</p> <p>22 A Because that is their expertise.</p> <p>23 Q Did the Histon lab follow its internal 24 quality control procedures when it performed the sample</p>

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<p>1 preparation?</p> <p>2 A They did.</p> <p>3 Q What about the sample embedding?</p> <p>4 A Same answer, they did.</p> <p>5 Q Microtomining?</p> <p>6 A Yes, they did.</p> <p>7 Q Staining procedures?</p> <p>8 A Yes, they did.</p> <p>9 Q Dr. MacLean, do we have traceability between</p> <p>10 the mesh used for the testing, the samples that were</p> <p>11 prepared and stained, and the results that were</p> <p>12 generated?</p> <p>13 A Yes, we do.</p> <p>14 Q How do you know that?</p> <p>15 A Because it's all in the documentation and</p> <p>16 it's all with the file structure that we've created on</p> <p>17 the folders.</p> <p>18 Q Would that be the same documentation that has</p> <p>19 been given over to the plaintiff lawyers?</p> <p>20 A It has.</p> <p>21 Q Represented in Exhibit 5?</p> <p>22 A That is correct.</p> <p>23 Q Dr. MacLean, does the proper documentation</p> <p>24 exist so that another scientist could repeat and verify</p>	<p>1 were either chemically or UV oxidized all the way</p> <p>2 through to the microtome samples that were stained and</p> <p>3 imaged by optical microscopy.</p> <p>4 Q Why is -- is traceability important --</p> <p>5 A It is.</p> <p>6 Q -- to a -- excuse me. Is traceability</p> <p>7 important to a scientist like yourself?</p> <p>8 A It is.</p> <p>9 Q How so?</p> <p>10 A For the very reasons we talked about. If</p> <p>11 someone wanted to re-create your work and verify it,</p> <p>12 you would want to have that traceability. If you</p> <p>13 wanted to go back and look and examine these things a</p> <p>14 second or third time with a fresh set of eyes, you</p> <p>15 would have that traceability.</p> <p>16 Q Dr. MacLean, let's talk about -- let's switch</p> <p>17 gears for a minute. You were asked early on in your</p> <p>18 deposition whether or not you were an expert in</p> <p>19 chemistry. Do you remember that line of questioning?</p> <p>20 A I do.</p> <p>21 Q How do you define being an expert in</p> <p>22 chemistry?</p> <p>23 A My definition is that you need to have</p> <p>24 advanced degrees, specifically in chemistry, and then</p>
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<p>1 your work?</p> <p>2 A Yes, absolutely.</p> <p>3 Q Dr. MacLean, have you maintained and</p> <p>4 preserved all the samples from your testing?</p> <p>5 A We have.</p> <p>6 Q Let's talk about the SEMs for just a minute</p> <p>7 that were done by Exponent on the oxidized samples,</p> <p>8 okay?</p> <p>9 A Correct.</p> <p>10 Q Do you have an electronic version of the lab</p> <p>11 notes that correspond to the work that was done?</p> <p>12 MR. THORNBURGH: Objection.</p> <p>13 THE WITNESS: Sorry, could you repeat</p> <p>14 that?</p> <p>15 MR. HUTCHINSON: Yeah.</p> <p>16 Q (By Mr. Hutchinson) Do you have an</p> <p>17 electronic version of the lab notes that correspond to</p> <p>18 the work that was done?</p> <p>19 A We have one-to-one correspondence between the</p> <p>20 micrographs that we took and the samples that they came</p> <p>21 from.</p> <p>22 Q And what does "one-to-one correspondence"</p> <p>23 mean to you?</p> <p>24 A We can trace back from the actual fibers that</p>	<p>1 you would have to have a significant amount of training</p> <p>2 and professional experience, as well, on top of that.</p> <p>3 Q Dr. MacLean, are you an expert in the</p> <p>4 chemical interaction of polymers and organic material?</p> <p>5 A I am.</p> <p>6 MR. THORNBURGH: Objection.</p> <p>7 THE WITNESS: I am.</p> <p>8 Q (By Mr. Hutchinson) How so?</p> <p>9 A Well, it's a combination of my specific</p> <p>10 organic polymer training and courses that I've taken in</p> <p>11 academia, and then in addition to the 20 plus years</p> <p>12 I've been studying these materials.</p> <p>13 Q Is that the type of chemistry that you would</p> <p>14 use and rely on in your work as a polymer scientist?</p> <p>15 A Yes.</p> <p>16 Q When we talk about ionic bonds forming</p> <p>17 between two molecules, what does that mean to you?</p> <p>18 A It means that you typically have one molecule</p> <p>19 that is either rich or deficient in electrons, and it</p> <p>20 has either a positive or negative charge associated</p> <p>21 with it, and it goes out and seeks other molecules with</p> <p>22 the opposite charge and ionically bonds.</p> <p>23 Q Do you have to be an expert in chemistry to</p> <p>24 understand that?</p>

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<p>1       A No. That is high school chemistry. That's  2 just an "ionic bond" definition, high school chemistry,  3 first-year undergraduate chemistry classes.</p> <p>4       Q Is that the type of chemistry that you work,  5 as a polymer scientist -- is that the -- strike that.</p> <p>6       Is that the type of chemistry that you use in  7 your practice as a polymer scientist at Exponent?</p> <p>8       A Sure. We look at ionic bonds, covalent  9 bonds, things of that nature, correct.</p> <p>10      Q What about hematoxylin and eosin chemical  11 staining, are you familiar with that process?</p> <p>12      A I am.</p> <p>13      Q Are you qualified to give opinions about how  14 that chemical process works?</p> <p>15      A Yes.</p> <p>16      Q Why?</p> <p>17       MR. THORNBURGH: Objection.</p> <p>18       THE WITNESS: For the reasons we just  19 talked about. Hematoxylin and eosin are  20 positively and negatively charged ionic  21 molecules, and they go out during the  22 staining process and they look for molecules  23 with opposite ionic charges to chemically  24 bond with, and those would be proteins that</p>	<p>1       witness, man.</p> <p>2       Q (By Mr. Hutchinson) Is that something that a  3 polymer scientist like yourself should understand?</p> <p>4       A Yes.</p> <p>5       Q Let's look at Exhibit 7 for a minute. Do you  6 have Exhibit 7 in front of you?</p> <p>7       A I do.</p> <p>8       Q And if we look on maybe the sixth or seventh  9 page in, under "Announcements," that includes a picture  10 of yourself, correct?</p> <p>11      A It does.</p> <p>12      Q And were you asked questions about this  13 paragraph?</p> <p>14      A I was.</p> <p>15      Q And you were asked questions about you  16 performing litigation and nonlitigation failure  17 analysis; is that right?</p> <p>18      A I was, correct.</p> <p>19      Q Do you recall being asked any questions by  20 the plaintiffs' lawyer about assisting industry clients  21 with product development?</p> <p>22      A I was not.</p> <p>23      Q Have you done that?</p> <p>24      A I have.</p>
<p style="text-align: center;">Page 379</p> <p>1       both carry positive and negative charges.</p> <p>2       Q (By Mr. Hutchinson) Is this type of  3 chemistry a basic understanding of polymer scientists?</p> <p>4       A It is. Ionic bonding is a basic chemistry  5 topic.</p> <p>6       Q And if the plaintiffs argue that you cannot  7 discuss the testing because you're a, quote -- you're  8 not, quote -- strike that.</p> <p>9       If the plaintiffs argue that you're not  10 allowed -- strike that.</p> <p>11      If the plaintiffs argue that you cannot  12 discuss your testing because you said you're not an  13 expert chemist, would you agree with that?</p> <p>14      A I would --</p> <p>15       MR. THORNBURGH: Objection.</p> <p>16       THE WITNESS: I would disagree with  17 that.</p> <p>18      Q (By Mr. Hutchinson) Why?</p> <p>19      A For the reasons we have talked about. I  20 just -- I just explained to you the ionic bonding that  21 needs to take place for the stain to hold.</p> <p>22       MR. THORNBURGH: Chad --</p> <p>23      Q (By Mr. Hutchinson) Is that --</p> <p>24       MR. THORNBURGH: -- quit leading your</p>	<p style="text-align: center;">Page 381</p> <p>1       Q Have you done that for medical devices?</p> <p>2       A I have.</p> <p>3       Q Have you done it for polypropylene medical  4 devices?</p> <p>5       A I have.</p> <p>6       Q For example, what?</p> <p>7       A Polypropylene syringes would be one of them.</p> <p>8       Q Did that include the addition of ingredients  9 to the base polymer, polypropylene?</p> <p>10      A Yes. It would -- the analysis would include  11 the whole polymer formulation, which would include the  12 base polymer, polypropylene, and any additives that  13 might be put into the material.</p> <p>14      Q Is that similar to what we've discussed today  15 about the differences between Prolene and  16 polypropylene?</p> <p>17      A Yes.</p> <p>18      Q You were asked questions about your work for  19 other companies who were defendants in litigation. Do  20 you remember that?</p> <p>21      A I do.</p> <p>22      Q Have you ever done any plaintiff expert work?</p> <p>23      A I have.</p> <p>24      Q You were asked questions about whether you</p>

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<p>1 reviewed explants from 37 plaintiffs. Do you remember 2 that line of questioning?</p> <p>3 A I do.</p> <p>4 Q Do you know when those explants were divided 5 among the parties?</p> <p>6 A I do not.</p> <p>7 Q Did the plaintiffs' lawyer tell you they were 8 divided among the parties just days before expert 9 disclosures were due?</p> <p>10 A They did not.</p> <p>11 MR. THORNBURGH: Objection.</p> <p>12 Mischaracterizes --</p> <p>13 Q (By Mr. Hutchinson) How long --</p> <p>14 MR. THORNBURGH: -- the events.</p> <p>15 Q (By Mr. Hutchinson) How long does it take to 16 clean an explant?</p> <p>17 A It can be a long time.</p> <p>18 Q Is cleaning an explant important?</p> <p>19 A It can be.</p> <p>20 Q Does it take more than two days?</p> <p>21 A It can.</p> <p>22 Q Why is cleaning an explant important?</p> <p>23 A Well, you want to remove any foreign tissue 24 or the formalin-fixed material that's on the outside of</p>	<p>1 Q You testified, when asked questions about the 2 Wood article, that there are other explanations such as 3 FAE. Do you happen to remember that?</p> <p>4 A I do.</p> <p>5 Q What does FAE stand for?</p> <p>6 A General classification of fatty acid esters.</p> <p>7 Q What are fatty acid esters?</p> <p>8 A They're the molecules I've talked about all 9 day today. It's an aliphatic tail with an ester 10 functionality at one end of the molecule.</p> <p>11 Q Do fatty acids and esters have C double bond 12 O's?</p> <p>13 A Yes, they do.</p> <p>14 Q What does it mean to have a C double bond O?</p> <p>15 A It means that you have a carbonyl group in 16 your molecule.</p> <p>17 Q And what's the significance of having a 18 carbonyl group in your molecule?</p> <p>19 A Well, because that can be -- that peak that 20 shows up with the ester can be in the same region as 21 where oxidation peaks up -- peaks show up in the IR 22 spectrum.</p> <p>23 Q Do you recall Mr. Thornburgh asking you 24 questions about Dr. Thames' testimony?</p>
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<p>1 the Prolene.</p> <p>2 Q Did the plaintiffs' lawyers designate some 3 experts in this litigation?</p> <p>4 A They have.</p> <p>5 Q Did they designate polymer scientists just 6 like yourself?</p> <p>7 A They have.</p> <p>8 Q Did they designate two polymer scientists?</p> <p>9 A They did.</p> <p>10 Q Who did they designate?</p> <p>11 A Dr. Jordi and Dr. Guelcher.</p> <p>12 Q Did Dr. Jordi and Dr. Guelcher analyze any of 13 the 37 explants, to your knowledge, according to their 14 reports?</p> <p>15 A According to their reports, no, they did not.</p> <p>16 Q I want to ask you a very quick question about 17 the Wood article. Does the Wood article use the word 18 "Prolene" in it?</p> <p>19 A It does not.</p> <p>20 Q Does the Wood article discuss Prolene?</p> <p>21 A It does not.</p> <p>22 Q What is the TVT mesh made up of in this 23 litigation?</p> <p>24 A Prolene.</p>	<p>1 A Yes.</p> <p>2 Q Did the plaintiffs' lawyer give you a full 3 copy of Dr. Thames' transcript?</p> <p>4 A They did not.</p> <p>5 Q Would you like to have seen the entire 6 transcript before answering questions about what 7 Dr. Thames said?</p> <p>8 A It would have been helpful to reread portions 9 of it, yes.</p> <p>10 Q Did the plaintiffs' lawyer read only --</p> <p>11 MR. THORNBURGH: Objection, leading.</p> <p>12 Come on.</p> <p>13 Q (By Mr. Hutchinson) Did the plaintiffs' 14 lawyer read only a portion of the transcript to you or 15 the entire transcript?</p> <p>16 A Just a portion.</p> <p>17 Q Did the plaintiffs' lawyer show you any 18 exhibits that were used with the deposition of 19 Dr. Thames?</p> <p>20 A No.</p> <p>21 Q Let's change gears for a minute, and I want 22 to ask you a couple of questions about antioxidants, 23 okay?</p> <p>24 A Okay.</p>

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<p>1       Q   And specifically I want to ask you questions 2   about primary and secondary antioxidants. 3       A   Okay. 4       Q   Does Ethicon put antioxidants in 5   polypropylene to make Prolene? 6       A   They do. 7       Q   What are the names of the two antioxidants 8   that they use? 9       A   They use Santanox R and DLTDP. 10      Q   Okay. Which one is a hindered phenol? 11      A   The hindered phenol is Santanox R. 12      Q   What is a hindered phenol? 13      A   It's a bulky -- excuse me, a bulky molecule 14   that actually goes out and scavenges free radicals. 15      Q   What is a thioester? 16      A   A thioester is a secondary antioxidant. 17      Q   What is -- in this litigation, is DLTDP what 18   you would consider a thioester? 19      A   It is. 20      Q   What does it mean to be a thioester? 21      A   It means it goes -- that molecule goes out 22   and searches for peroxide-type molecules and 23   neutralizes them so they can't cause damage to the 24   underlying polymer.</p>	<p>1       A   No. 2       Q   Do you know how many days Dr. Barbolt was 3   deposed? 4       A   I do not. 5       Q   Did the plaintiffs' lawyer show you one day 6   or two days of his deposition? 7       A   I don't recall. 8       Q   Let's look at Exhibit 10 for me. 9       A   Okay. 10      Q   Are you there with me? 11      A   I am. 12      Q   Do you remember the plaintiffs' lawyer asking 13   you questions about this document? 14      A   I do. 15      Q   Let's look at the third paragraph, first 16   sentence. It says, "Polymer degradation is a natural 17   phenomenon that cannot be totally stopped." Do you see 18   that? 19      A   I do. 20      Q   Did I read that correctly? 21      A   You did. 22      Q   Do you remember the plaintiffs' lawyer asking 23   you questions about that paragraph? 24      A   I do.</p>
<p style="text-align: center;">Page 387</p> <p>1       Q   The plaintiffs' lawyer asked you questions 2   about what Dr. Barbolt said in his deposition 3   testimony. Do you remember that? 4       A   I do. 5       Q   Were you shown the full transcript of 6   Dr. Barbolt? 7       A   I was -- I was not. 8       Q   Did the plaintiffs' lawyer read selective 9   pages of Dr. Barbolt's transcript to you? 10      A   Yes. 11      Q   Do you remember the plaintiffs' lawyer asking 12   you about page 409 -- 13      A   I do. 14      Q   -- of the transcript? 15      A   I do. 16      Q   Did the plaintiffs' lawyer show you 408 other 17   pages of the transcript? 18      A   They did not. 19      Q   Did the plaintiffs' lawyer show you any 20   exhibits that were used with Dr. Barbolt? 21      A   They did not. 22      Q   Did the plaintiffs' lawyer show you any 23   follow-up questions that Ethicon's lawyers asked of 24   Dr. Barbolt?</p>	<p style="text-align: center;">Page 389</p> <p>1       Q   Dr. MacLean, have you seen any evidence in 2   this litigation that Prolene mesh degrades in the body 3   over the lifetime of the patient? 4       A   I have not. 5       Q   Dr. MacLean, you were asked questions earlier 6   about whether or not you did any GPC analysis. Do you 7   remember that question? 8       A   I do. 9       Q   What does GPC stand for? 10      A   Gel permeation chromatography. 11      Q   Did you do any gel permeation chromatography 12   to determine loss of molecular weight? 13      A   I did not. 14      Q   Why not? 15      A   For my experiments, it was not necessary. 16      Q   Why wasn't it necessary? 17      A   Because my experiments were focused on 18   determining whether oxidized or unoxidized Prolene 19   would actually stain in H&amp;E staining. 20      MR. HUTCHINSON: Let's go off the 21   record. I think I'm about done. 22      THE VIDEOGRAPHER: We are now going off 23   the video record. The time is currently 24   7:47 p.m.</p>

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1	(Recess taken.)	1	hematoxylin does not stain cell membranes, correct?
2	THE VIDEOGRAPHER: We are now back on	2	A According to my research, eosin stains
3	the video record. The time is currently	3	cellular membranes. Cellular membranes have a positive
4	7:49 p.m.	4	charge, and eosin is a negatively charged ion.
5	MR. HUTCHINSON: Dr. MacLean, I don't	5	Q Does it stain cytoplasmic components?
6	have any more questions. Thank you for your	6	MR. HUTCHINSON: Object to form.
7	time.	7	THE WITNESS: Eosin does.
8	THE WITNESS: Okay. Thank you.	8	Q (By Mr. Thornburgh) Okay, not hematoxylin?
9	FURTHER EXAMINATION	9	A If it has a negative -- if it has a negative
10	BY MR. THORNBURGH:	10	charge, if the ion that it's seeking out has a negative
11	Q All right, Doctor. Doctor, what is	11	charge, hematoxylin will be the compound that will
12	hematoxylin stain?	12	stain with it. If it's seeking something that has a
13	A What is hematoxylin stain?	13	positive charge, eosin will be the staining element
14	Q Uh-huh.	14	that will stain that --
15	A It's an ionic stain that we talked about a	15	MR. THORNBURGH: We've got to change the
16	few minutes ago that has the ability to stain charged	16	tape.
17	particles, charged molecules.	17	A -- biological material.
18	Q What are some examples of some charged	18	MR. THORNBURGH: We have to change the
19	particles or charged --	19	tape.
20	A Well, they're in the --	20	THE VIDEOGRAPHER: We are now going off
21	Q -- molecules?	21	the video record. The time is currently
22	A -- they're in the report. There's proteins,	22	7:52 p.m. This is the end of Tape No. 6.
23	amino acids, polypeptides. All of them that are found	23	(Off the record.)
24	naturally in the body have ionic charges to them.	24	THE VIDEOGRAPHER: We are now back on
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1	Q Is it your understanding that hematoxin	1	the video record with Tape No. 7. The time
2	[sic] --	2	is currently 7:55 p.m.
3	MR. HUTCHINSON: Hematoxylin.	3	Q (By Mr. Thornburgh) Doctor, before we went
4	Q -- hematoxylin stains extracellular proteins?	4	off the record, we were talking about the types of
5	A It stains a specific protein with a negative	5	biologic material that is stained by hematoxylin. Does
6	charge.	6	hematoxylin stain nuclei? Can you tell me without
7	Q What about extracellular proteins?	7	looking at the report?
8	A It would depend on the charge.	8	A I can. It does.
9	Q What about cell membranes? Doctor?	9	Q What about DNA -- or, sorry, strike that.
10	A Yeah, I want to give you an answer that's	10	What about amino acids?
11	correct.	11	A It depends on the charge in the amino acids.
12	Q Can you tell me off the top of your head?	12	There can be amino acids that have positive charges,
13	MR. HUTCHINSON: No, Dan, we're not	13	there can be amino acids that have negative charges,
14	doing that. He's -- the witness has told you	14	and their respective staining element will take care of
15	he's trying to give you an answer that's	15	the positive or negative ionic bonds that are in those
16	correct.	16	amino acids.
17	Q (By Mr. Thornburgh) You still need some	17	Q What is the role of mordants in the
18	time, Doctor?	18	histological stains?
19	A Yes, I do.	19	A It's a bridge for hematoxylin.
20	No, eosin is the proper staining mechanism	20	Q A bridge -- can you explain that a little
21	for cellular membranes.	21	bit?
22	Q You said -- what did you say? I'm sorry.	22	A Sure. So hematoxylin converts to hematin,
23	A Eosin.	23	and then you need the mordant from hematin to actually
24	Q So it's your -- it's your opinion that	24	cause the ionic bond to take place, which is a positive

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<p>1 charge, the cation, to actually wind up combining with 2 a negative molecule, negatively charged molecule that 3 it's trying to stain.</p> <p>4 Q Is polypropylene charged?</p> <p>5 A It is not. It's not ionically charged.</p> <p>6 Q What is it charged by?</p> <p>7 MR. HUTCHINSON: Object to form.</p> <p>8 THE WITNESS: It's not charging 9 anything. I'm just trying to stay within the 10 confines of staining, ionic staining. And 11 polypropylene, nor oxidized polypropylene, 12 and Prolene and oxidized Prolene, none of 13 them are ionic in nature.</p> <p>14 Q (By Mr. Thornburgh) Do you have any 15 references that you rely on for that?</p> <p>16 A It is fundamental polymer science that those 17 are not ionic molecules.</p> <p>18 Q Is it your -- I'm trying -- I'm just trying 19 to understand your opinions. Is it your opinion that 20 substances only possess -- substances that only possess 21 a charge can stain?</p> <p>22 A An ionic charge. It has -- it's seeking out 23 molecules that are either in surplus or are deficient 24 with electrons. And polypropylene, as a molecular</p>	<p>1 to show you some transcript testimony from Dr. Barbolt 2 to demonstrate that somehow I had misled you or 3 misrepresented something to you, but he did not ask you 4 or show you any transcript testimony from Dr. Barbolt, 5 did he?</p> <p>6 A He did not.</p> <p>7 Q When was the last time you actually performed 8 GPC analysis?</p> <p>9 A Me personally or used it as a tool in one of 10 my investigations?</p> <p>11 Q You personally.</p> <p>12 A Personally was probably in graduate school. 13 But I've used that tool for the last 20 years in 14 polymer investigations.</p> <p>15 Q When was the last time you cleaned -- strike 16 that.</p> <p>17 When was the last time you dissolved tissue 18 from an explanted medical device, in other words, 19 cleaned it with some type of reagent?</p> <p>20 A I have not -- I have not cleaned tissue from 21 an explanted medical device.</p> <p>22 Q When was the last time you performed DSC 23 testing?</p> <p>24 A Personally?</p>
<p style="text-align: center;">Page 395</p> <p>1 structure, is not deficient in electrons, nor does it 2 have a surplus of electrons in its -- in its neat 3 state, N-E-A-T, state.</p> <p>4 Q Do you routinely use histological staining?</p> <p>5 A I do not.</p> <p>6 Q When was the last time, other than this case, 7 that you asked for or ordered some H&amp;E staining to be 8 done of explanted specimens?</p> <p>9 A This was the first time that I've actually 10 done that, and that's exactly why we went to a 11 third-party lab that specializes in it.</p> <p>12 Q Defense counsel asked you or discussed with 13 you questions I asked or -- strike that.</p> <p>14 Defense counsel asked you whether I had only 15 read an excerpt of Dr. Thamess deposition testimony. 16 Do you recall that?</p> <p>17 A I do.</p> <p>18 Q Defense counsel had an opportunity to correct 19 any perceived misinformation or inaccurate information 20 on direct examination, but he didn't ask you a single 21 question or show you a single excerpt from the Thamess 22 deposition transcript, did he?</p> <p>23 A He did not.</p> <p>24 Q Same with Dr. Barbolt, he had an opportunity</p>	<p style="text-align: center;">Page 397</p> <p>1 Q Yes.</p> <p>2 A Again, probably in graduate school is when I 3 last ran the instrumentation. I run DSC on polymer 4 samples, you know, weekly -- weekly and monthly, 5 rather.</p> <p>6 Q When was the last time you performed FTIR 7 analysis outside of this case?</p> <p>8 A Probably the same answer. Probably graduate 9 school when I last had my hands on the instrumentation. 10 And again, that's a technique that -- and a tool that 11 we use in polymer science on a weekly/monthly basis on 12 all of our investigations.</p> <p>13 Q And graduate school was 18, 20 years ago?</p> <p>14 A No, no.</p> <p>15 Q Fifteen years ago?</p> <p>16 A 2004 through 2007.</p> <p>17 Q Now, defense counsel had represented that the 18 division of certain TVT explants occurred right before 19 expert disclosures were due. You have no idea when 20 expert disclosures were due, correct?</p> <p>21 A I have no idea.</p> <p>22 Q You have no idea and didn't know that the 23 plaintiffs' disclosures were due before the 24 plaintiffs' -- before the defendant's disclosures were</p>

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<p>1 due right around the time of the division, you had no 2 idea about that, right?</p> <p>3 A I had no idea.</p> <p>4 Q And do you understand that Dr. Ong, an 5 Exponent employee, an expert in mesh litigation, is the 6 doctor that actually went up to Toronto and divided the 7 TVT meshes?</p> <p>8 MR. HUTCHINSON: Object to form.</p> <p>9 THE WITNESS: I'm not aware of that.</p> <p>10 I'm not aware of that.</p> <p>11 Q (By Mr. Thornburgh) And Dr. Ong is your 12 colleague, right?</p> <p>13 A He is my -- he is an Exponent employee, 14 correct.</p> <p>15 Q You know Dr. Ong, right?</p> <p>16 A I know him.</p> <p>17 Q He doesn't live -- he practices out of the 18 Philadelphia office. You're in the, what, Maryland 19 office?</p> <p>20 A My office is in Bowie, Maryland, correct.</p> <p>21 Q How far is -- that's a -- that's a train 22 ride, right?</p> <p>23 A You can -- you can travel it by train.</p> <p>24 Q And Dr. Ong didn't reach out to you and ask</p>	<p>1 goods were transferred. I have no idea about 2 that.</p> <p>3 Q (By Mr. Thornburgh) Defense counsel asked 4 you --</p> <p>5 (Interruption in the proceedings and 6 discussion off the written record.)</p> <p>7 Q (By Mr. Thornburgh) Defense counsel 8 asked you about -- asked questions that I had 9 asked you about, and he said, "Do you remember when 10 Mr. Thornburgh asked you if you ever represented -- or 11 have ever been retained as an expert on behalf of 12 plaintiffs?" Do you remember that question?</p> <p>13 A I do.</p> <p>14 Q And you said yes?</p> <p>15 A I did.</p> <p>16 Q But when you testified -- your testimony 17 during my cross-examination was that, yes, you had 18 represented plaintiffs, but those plaintiffs were 19 corporate plaintiffs, correct?</p> <p>20 A Correct. Both of those answers are true.</p> <p>21 Q You never represented a plaintiff who had 22 been harmed by a corporate defendant?</p> <p>23 MR. HUTCHINSON: Object to form.</p> <p>24 THE WITNESS: I have not been retained</p>
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<p>1 you if you could conduct -- strike that.</p> <p>2 Defense counsel, Chad or other lawyers for 3 Ethicon, never reached out to you to ask you if you 4 could conduct either the cleaning of the mesh TVT 5 specimens or the analysis of the TVT specimens, 6 correct?</p> <p>7 A No one reached out to me to do that work, 8 correct.</p> <p>9 Q This is despite the fact that Dr. Ong, your 10 colleague at Exponent, did the division?</p> <p>11 A As reported by you.</p> <p>12 Q Have you looked at the expert report of 13 Dr. Thamess?</p> <p>14 A In this matter?</p> <p>15 Q Yes.</p> <p>16 A I have not.</p> <p>17 Q And you know Dr. Thamess is in Mississippi, 18 right?</p> <p>19 A I do.</p> <p>20 Q So Dr. Ong shipped the mesh TVT specimens 21 from Philadelphia to Jackson, Mississippi; is that 22 your -- that's where Dr. Thamess lives?</p> <p>23 MR. HUTCHINSON: Object to form.</p> <p>24 THE WITNESS: I have no idea if any</p>	<p>1 by a firm that has been hired to represent an 2 individual plaintiff.</p> <p>3 Q (By Mr. Thornburgh) I looked at the Exhibit 4 No. 5, which was the thumb drive --</p> <p>5 A Correct.</p> <p>6 Q -- and I still couldn't find the lab 7 notebooks from any of your --</p> <p>8 A It's in the -- it's in the histology folder.</p> <p>9 Q Okay. So Dr. Beright's [sic] --</p> <p>10 A Benight.</p> <p>11 Q -- Benight's lab notebooks are in your 12 folder -- are in that folder?</p> <p>13 A Correct. There's a lab notebook -- there's 14 an electronic version of our lab notebook as well as a 15 log of the -- all of the micrographs that were taken.</p> <p>16 MR. HUTCHINSON: Just let the record 17 reflect that the receptionist has come in and 18 advised that they're trying to turn the 19 lights off. So, Dan, I'm going to ask that 20 you please speed up the process if you have 21 any more questions. Do you have any more 22 questions?</p> <p>23 MR. THORNBURGH: Let me just look at my 24 notes, buddy.</p>

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<p>1           MR. HUTCHINSON: Okay.</p> <p>2           Q (By Mr. Thornburgh) Couple more questions.</p> <p>3   I think your testimony was that the ionic bond science</p> <p>4   that you used in this case is basic science that's</p> <p>5   performed by high-schoolers?</p> <p>6           MR. HUTCHINSON: Object to form,</p> <p>7   mischaracterizes --</p> <p>8           Q (By Mr. Thornburgh) Or learned in high</p> <p>9   school?</p> <p>10          MR. HUTCHINSON: Dan, we don't have time</p> <p>11   to mischaracterize testimony.</p> <p>12          MR. THORNBURGH: I'm not. That's what</p> <p>13   the testimony is.</p> <p>14          MR. HUTCHINSON: The receptionist has</p> <p>15   asked that we leave because they're trying to</p> <p>16   turn the lights off. So would you please</p> <p>17   rephrase.</p> <p>18          MR. THORNBURGH: These are direct to --</p> <p>19   these are --</p> <p>20          MR. HUTCHINSON: Would you please</p> <p>21   rephrase your question.</p> <p>22          Q (By Mr. Thornburgh) Your testimony, I</p> <p>23   believe, was that high-schoolers learn about ionic</p> <p>24   bonds, it's basic chemistry.</p>	<p>1           A I have personally not done it, correct.</p> <p>2           Q Do you know what's involved with the H&amp;E</p> <p>3   staining process?</p> <p>4           A Sure. It's listed in my report. There's a</p> <p>5   complete sequence of the H&amp;E staining.</p> <p>6           Q I understand that. I also know you had help</p> <p>7   with other folks at Exponent, and I'm not faulting you</p> <p>8   for that --</p> <p>9           MR. HUTCHINSON: Hey, guys, hold on a</p> <p>10   minute.</p> <p>11          Q -- but do you -- do you know the --</p> <p>12          MR. HUTCHINSON: Do you have a question,</p> <p>13   Dan?</p> <p>14          MR. THORNBURGH: Yeah.</p> <p>15          Q (By Mr. Thornburgh) Do you -- what is the --</p> <p>16          MR. HUTCHINSON: All right, well, state</p> <p>17   your question.</p> <p>18          Q (By Mr. Thornburgh) What is the process that</p> <p>19   was performed or is performed in H&amp;E staining of</p> <p>20   explanted polypropylene -- I'm sorry, of pristine</p> <p>21   degraded polypropylene mesh?</p> <p>22          MR. HUTCHINSON: Object to the form.</p> <p>23          THE WITNESS: I'm just going to --</p> <p>24          MR. HUTCHINSON: Been asked and</p>
<p style="text-align: center;">Page 403</p> <p>1           A Ionic bonds are in basic chemistry books,</p> <p>2   textbooks, classes, et cetera, yes.</p> <p>3           Q And when was the last time you -- when was</p> <p>4   the last time you -- did you learn ionic bonds in high</p> <p>5   school?</p> <p>6           A Yeah.</p> <p>7           Q Okay.</p> <p>8           A In high school chemistry, sure.</p> <p>9           Q Did you take college chemistry?</p> <p>10          A I did.</p> <p>11          Q Was that --</p> <p>12          A Several courses in high school -- excuse me,</p> <p>13   in college-level chemistry.</p> <p>14          Q I'm sorry, several courses?</p> <p>15          A Several courses in college-level chemistry,</p> <p>16   correct.</p> <p>17          Q And did those courses deal with ionic bonds</p> <p>18   of hematoxylin or eosin?</p> <p>19          A Not specifically those two compounds, but</p> <p>20   you're talking about a bond chemistry that's just</p> <p>21   fundamental to chemistry.</p> <p>22          Q And the reason why -- I think you testified</p> <p>23   the reason why you sent the mesh explants to this third</p> <p>24   party was because you haven't done H&amp;E staining, right?</p>	<p style="text-align: center;">Page 405</p> <p>1           answered.</p> <p>2          THE WITNESS: I'm just going to wind up</p> <p>3   reading the process that's clearly outlined</p> <p>4   in our report.</p> <p>5          MR. THORNBURGH: Okay.</p> <p>6          THE WITNESS: If you'd like me to do</p> <p>7   that, I will.</p> <p>8          Q (By Mr. Thornburgh) Is that a process that</p> <p>9   you learned through this third party?</p> <p>10          A Yes, absolutely.</p> <p>11          Q So they -- you called them up and asked them</p> <p>12   what the process was?</p> <p>13          A It was a bit more -- it was a bit more to it</p> <p>14   than that. We gave them the staining protocol that</p> <p>15   Dr. Iakovlev had used, and we said, "Can you create a</p> <p>16   staining process that mimics what he did," and that's</p> <p>17   what they did for us.</p> <p>18          Q Are there different -- I'm almost done. Are</p> <p>19   there different types of H&amp;E staining?</p> <p>20          A There are.</p> <p>21          Q And what are the different types of H&amp;E</p> <p>22   staining?</p> <p>23          A I'm not -- I'm not sure. I just know that</p> <p>24   there are different variants of hematoxylin, for</p>

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<p>1 example.</p> <p>2 Q Do you know what variant was used by</p> <p>3 Dr. Iakovlev?</p> <p>4 A I believe -- I believe he used a water-based,</p> <p>5 and then I believe we used an alcohol-based.</p> <p>6 Q And what would -- do you know what the --</p> <p>7 why -- strike that.</p> <p>8 So you believe he used a water-based and your</p> <p>9 third party used an alcohol-based?</p> <p>10 A That's what I believe, correct.</p> <p>11 Q And do you know why this third party that you</p> <p>12 retained to help you with this analysis did an alcohol</p> <p>13 base rather than a water base?</p> <p>14 A Because that's the type of -- those are the</p> <p>15 specific H&amp;E stains that they have and they use on</p> <p>16 site.</p> <p>17 Q Do you know what would -- could have been</p> <p>18 different had you used the same H&amp;E staining that was</p> <p>19 used by Dr. Iakovlev?</p> <p>20 A My understanding, there would be no</p> <p>21 difference.</p> <p>22 Q Why do -- why do -- strike that.</p> <p>23 Why do some labs use alcohol-based H&amp;E</p> <p>24 staining versus water stain?</p>	<p>1 8:11 p.m.</p> <p>2 (Off the record.)</p> <p>3 THE VIDEOGRAPHER: We are now back on</p> <p>4 the video record. The time is currently</p> <p>5 8:12 p.m.</p> <p>6 Q (By Mr. Thornburgh) The H&amp;E slides that were</p> <p>7 created, were those done originally on unstained</p> <p>8 charged or uncharged slides?</p> <p>9 A I believe the slides were charged, slightly</p> <p>10 charged. That's why you get some degree of adhesion</p> <p>11 between the microtome sample and the glass prior to</p> <p>12 putting them in the baths.</p> <p>13 Q So yours were charged?</p> <p>14 A I believe so.</p> <p>15 Q Okay. And do you know what Dr. Iakovlev's</p> <p>16 were?</p> <p>17 A I don't recall.</p> <p>18 Q Would it impact the results if Dr. Iakovlev</p> <p>19 used uncharged stains and you used charged?</p> <p>20 A Not that we've been advised by the</p> <p>21 laboratory.</p> <p>22 Q Is that a question that you asked the</p> <p>23 laboratory?</p> <p>24 A We asked them the general question, giving</p>
<p style="text-align: center;">Page 407</p> <p>1 A I think it's just a matter of what chemistry</p> <p>2 that you decide to use in your lab. All of these</p> <p>3 stains that -- these number of different stains exist.</p> <p>4 Some labs use Stain A; some labs use Stain B.</p> <p>5 Q Did you ask this third-party lab to use the</p> <p>6 same H&amp;E staining that was used by Dr. Iakovlev?</p> <p>7 A I did not. We asked them if we -- if</p> <p>8 we [sic] thought it was going to have any meaningful</p> <p>9 impact on the experiment or the results, and they</p> <p>10 assured us the answer was no.</p> <p>11 MR. HUTCHINSON: Dan, any other</p> <p>12 questions? I'd like to be courteous to our</p> <p>13 receptionist.</p> <p>14 MR. MORRIS: Yeah, we do. Let's go off</p> <p>15 the record for two minutes.</p> <p>16 MR. HUTCHINSON: You do have questions?</p> <p>17 MR. MORRIS: Maybe one more.</p> <p>18 MR. HUTCHINSON: All right, well, I want</p> <p>19 to -- I just want to make the record to</p> <p>20 reflect the receptionist has asked that we</p> <p>21 leave multiple times, and we're trying to be</p> <p>22 courteous to the receptionist.</p> <p>23 THE VIDEOGRAPHER: We are now going off</p> <p>24 the video record. The time is currently</p>	<p style="text-align: center;">Page 409</p> <p>1 the protocol that Dr. Iakovlev had presented to us,</p> <p>2 whether there would be any meaningful differences</p> <p>3 between the two, and they assured us the answer was no.</p> <p>4 Q What's the purpose of uncharged versus</p> <p>5 charged slides?</p> <p>6 A What's the purpose?</p> <p>7 Q Yeah.</p> <p>8 MR. HUTCHINSON: Object to form.</p> <p>9 Q (By Mr. Thornburgh) What's the significance</p> <p>10 in H&amp;E staining of degraded polypropylene of using</p> <p>11 uncharged versus charged slides?</p> <p>12 A I don't see how there's any significance to</p> <p>13 that.</p> <p>14 MR. HUTCHINSON: Any other questions,</p> <p>15 Dan?</p> <p>16 Q (By Mr. Thornburgh) And did you say that</p> <p>17 this third-party lab's protocols are all produced in</p> <p>18 Exhibit No. 5?</p> <p>19 A Yeah, and they're also in the report.</p> <p>20 MR. THORNBURGH: Okay, no questions.</p> <p>21 MR. HUTCHINSON: No questions? Thanks.</p> <p>22 FURTHER EXAMINATION</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q Dr. MacLean, I have one follow-up question.</p>

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1	Could Dr. Iakovlev take your samples and try to stain	1	INDEX
2	them on his own?	2	
3	A He could.	3	
4	MR. HUTCHINSON: Okay. I don't have any	4	EXAMINATIONS
5	questions. Thank you so much.	5	Examination by Mr. Thornburgh ..... 7
6	MR. THORNBURGH: Could Dr. Iakovlev take	6	Examination by Mr. Hutchinson ..... 362
7	your samples and try to stain them on his	7	Further Examination by Mr. Thornburgh ..... 390
8	own?	8	Further Examination by Mr. Hutchinson ..... 409
9	MR. HUTCHINSON: Yeah.	9	---
10	MR. THORNBURGH: I don't understand the	10	EXHIBITS
11	question. How --	11	Exhibit Page
12	MR. HUTCHINSON: Okay. Well, I'm not	11	Exhibit 1 ..... 8
13	asking you the question. Do you have any	12	Notice of Videotaped Deposition Pursuant to
14	further questions?	12	Rule 30 and Document Requests Pursuant to Rule
15	MR. THORNBURGH: No.	13	34 of Steven B. Maclean, Ph.D., P.E.
16	MR. HUTCHINSON: All right.	14	Exhibit 2 ..... 9
17	THE VIDEOGRAPHER: We are now going off	14	MacLean Expert Reports (binder)
18	the video record. The time is currently	15	Exhibit 3 ..... 9
19	8:15 p.m. This is the end of Tape No. 7 and	15	Deposition Materials, September 29, 2015
20	the end of the deposition.	16	(binder)
21	(Deposition concluded at 8:15 p.m.)	17	Exhibit 4 ..... 10
22		17	1980s Microcrack Committee Documents (binder)
23		18	Exhibit 5 ..... 10
24		19	Thumb drive
		20	Exhibit 6 ..... 12
		20	Exemplar TVT mesh
		21	Exhibit 7 ..... 33
		22	FAPSIG Newsletter, May 2012
		23	
		24	
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1	C E R T I F I C A T E	1	INDEX (Cont'd)
2		2	
3	STATE OF GEORGIA	3	Exhibit Page
4	COUNTY OF COBB	4	Exhibit 8 ..... 101
5		5	Article, "Materials characterization and
6	I, MICHELLE M. BOUDREAUX, do hereby certify	5	histological analysis of explanted
7	that STEVEN MACLEAN, Ph.D., P.E., the witness whose	6	polypropylene, PTFE, and PET hernia meshes
8	deposition is hereinbefore set forth, was duly sworn by	6	from an individual patient" (Wood, et al.)
9	me and that such deposition is a true record of the	7	Exhibit 9 ..... 152
10	testimony given by such witness.	7	February 2003 email chain with attachments
11		8	(ETH.MESH.02268618, etc.)
12	I further certify that I am not related to	9	Exhibit 10 ..... 174
13	any of the parties to this action by blood or marriage	9	Equistar Technical Tip, "Additives:
14	and that I am in no way interested in the outcome of	10	Antioxidants"
15	this matter.	11	Exhibit 11 ..... 176
16		11	September 30, 1987 letter to Dr. A.J. Melveger
17	IN WITNESS WHEREOF, I have hereunto set my	12	from D.F. Burkley
18	hand this 1st day of October 2015.	13	Exhibit 12 ..... 187
19		13	Article, "Mechanical and biochemical effects
20		14	of man-made fibres and metals in the human
21	MICHELLE M. BOUDREAUX, RPR	14	eye, a SEM-study (Jongebloed, et al.)
22		15	Exhibit 13 ..... 205
23		16	November 13, 1984 letter to Dr. J. McDivitt
24		16	from Daniel F. Burkley
		17	Exhibit 14 ..... 230
		18	Ethicon, ERF Accession No. 85-219, Project No.
		19	16102 (September 20, 1988)
		20	Exhibit 15 ..... 232
		20	August 10, 1990 letter to Kren Braun from
		21	E. Lindemann
		21	Exhibit 16 ..... 236
		22	May 30, 1985 letter to Kronenthal, Lilienfeld,
		22	and Marshall from Cholvin
		23	
		24	

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3 Exhibit Page  
4 Exhibit 17 ..... 256  
5 Seven Year Data for Ten Year Prolene Study:  
6 ERF 85-219  
7 Exhibit 18 ..... 270  
8 Seven Year Dog Study (composite exhibit, white  
9 binder)  
10 Exhibit 19 ..... 307  
11 November 5, 1984 letter to Dr. A.J. Melveger  
12 from Peter Moy, Ph.D.  
13 Exhibit 20.....  
14 (inadvertently not marked for identification)  
15 Exhibit 21 ..... 326  
16 March 23, 1983 letter to Dr. A. Lunn from  
17 B. Matlaga  
18 Exhibit 22 ..... 347  
19 Article, "Comparison of the In Vivo Behavior  
20 of Polyvinylidene Fluoride and Polypropylene  
21 Sutures Used in Vascular Surgery"  
22 (Mary, et al.)  
23  
24

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1 ERRATA SHEET FOR THE TRANSCRIPT OF:  
2 Case Name: In Re: Ethicon Pelvic Repair System  
3 Deposition Date: September 29, 2015  
4 Deponent: Steven B. MacLean, Ph.D., P.E.  
5 Pg. Ln. Now Reads Should Read Reason

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Signature of Deponent

20  
21 SUBSCRIBED AND SWORN BEFORE ME  
22 THIS \_\_\_\_ DAY OF \_\_\_\_ 20 \_\_\_\_.

23  
24 (SIGNATURE OF NOTARY PUBLIC)  
MY COMMISSION EXPIRES: \_\_\_\_\_

105 (Pages 414 to 415)

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